



FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES  
COMMISSIONER ADAM H. PUTNAM

---

December 4, 2015

Debra Rate, Ph.D.  
Acting Emergency Response Team Leader  
U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
Risk Integration, Minor Use and  
Emergency Response Branch  
Room S4900, One Potomac Yard  
2777 Crystal Drive  
Arlington, Virginia 22202

Dear Dr. Rate:

Enclosed is a FIFRA Section 18 specific exemption petition submitted on behalf of Florida Fruit and Vegetable Association (FFVA) for the use of FireWall™ 50 WP (streptomycin sulfate; EPA Reg. No. 80990-3), FireLine™ 17 WP (oxytetracycline hydrochloride; EPA Reg. No. 80990-1), and Mycoshield® (oxytetracycline calcium complex; EPA Reg. No. 55146-97) to control *Candidatus Liberibacter asiaticus* (CLas) bacterium in citrus.

*Candidatus Liberibacter asiaticus*, the bacterium causing citrus greening disease, has been documented in Florida citrus since 2005. Since its establishment, efforts to control the spread and progression of the disease have largely focused on removal of diseased trees, nutritional support, as well as rigorous efforts to control the Asian citrus psyllid, the vector for this disease. However, more recently, research efforts have shifted towards a focus on both ridding infected trees of the pathogen as well as slowing the progression of the disease through the use of antimicrobial agents.

The requested exemption stipulates that no more than 1.35 pounds streptomycin sulfate (2.07 pounds of FireWall) per acre per year and no more than 2.04 pounds oxytetracycline equivalent (potentially from FireLine and Mycoshield) per acre per year. Florida has over 388,000 acres of commercial citrus throughout the state. Additional details of the proposed use pattern are found within the narrative document of this petition.

The Department has reviewed and/or consulted with the affected agencies and determined that use of FireWall, FireLine and Mycoshield antimicrobials under the conditions of this proposed specific exemption will not pose a risk to endangered species (Department assessment to follow).

Dr. Debra Rate  
December 4, 2015  
Page Two

Please send any correspondence on this request to: Mr. Charlie L. Clark, Environmental Administrator, Pesticide Registration Review Section, Bureau of Scientific Evaluation and Technical Assistance, Division of Agricultural Environmental Services, 3125 Conner Boulevard, Building #6, Tallahassee, Florida 32399-1650, Phone 850-617-7940, e-mail: [Charlie.Clark@FreshFromFlorida.com](mailto:Charlie.Clark@FreshFromFlorida.com).

Sincerely,



Adam H. Putnam  
Commissioner of Agriculture

AHP/dd

Attachment

Dr. Debra Rate  
December 4, 2015  
Page Three

cc: Mr. Mike Joyner  
Dr. Lisa Conti  
Mr. Matt Joyner  
Dr. Joseph Joyce  
Mr. John Hoblick  
Mr. Randy Dominy  
Mr. Philip Beard  
Dr. Fred Fishel  
Mr. Daniel Botts  
Mr. Michael Aerts  
Dr. Michael Rogers  
Dr. Harold Browning  
Dr. Michelle S. Samuel-Foo  
Mr. Anderson H. Rackley  
Ms. Kelly Friend  
Dr. Davis Daiker  
Mr. Charlie Clark  
Ms. Sarah Oglesby  
Mr. Dale Dubberly  
Mr. Neil Richmond  
Ms. Jo Marie Cook  
Ms. Patty Lucas  
Mr. Tau Richardson  
Mr. Tom Jerkins  
Mr. Mark Trimmer  
Mr. Bill Bewlay

**EMERGENCY EXEMPTION REQUEST**

**(Specific Exemption)**

**FOR THE USE OF THE ANTIBIOTICS**

**FireWall™ 50WP Fungicide/Bactericide (streptomycin sulfate)**

**FireLine™ 17WP (oxytetracycline hydrochloride)**

**Mycoshield® (oxytetracycline calcium)**

**TO SUPPRESS**

**Huanglongbing (HLB) (*Candidatus Liberibacter asiaticus*)**

**and IMPROVE TREE HEALTH**

**ON**

**Citrus**

**IN FLORIDA**

**December 2, 2015**

## TABLE OF CONTENTS

<u>CONTACT PERSON(S) AND QUALIFIED EXPERTS (166.20(a)(1))</u> .....	3
<u>DESCRIPTION OF PESTICIDE REQUESTED (166.20(a)(2))</u> .....	3
<u>DESCRIPTION OF PROPOSED USE (166.20(a)(3))</u> .....	4
<u>ALTERNATIVE METHODS OF CONTROL (166.20(a)(4))</u> .....	12
<u>EFFICACY OF USE PROPOSED UNDER SECTION 18 (166.20(a)(5))</u> .....	17
<u>DISCUSSION OF RESIDUES IN FOOD (166.20(a)(6))</u> .....	23
<u>DISCUSSION OF RISK INFORMATION (166.20(a)(7))</u> .....	25
<u>FQPA INFORMATION (OCTOBER 24, 1996 EPA LETTER)</u> .....	31
<u>COORDINATION WITH OTHER AFFECTED FEDERAL, STATE, AND LOCAL AGENCIES (166.20(a)(8))</u> .....	31
<u>NOTIFICATION OF REGISTRANT (166.20(a)(9))</u> .....	31
<u>DESCRIPTION OF ENFORCEMENT PROGRAM (166.20(a)(10))</u> .....	32
<u>REPEAT USES (166.20(a)(11))</u> .....	32
<u>PROGRESS TOWARD REGISTRATION (166.20(b)(2)(ii))</u> .....	32
<u>NAME OF PEST (166.20(b)(1))</u> .....	33
<u>DISCUSSION OF THE EMERGENCY CONDITION (166.20(b)(2))</u> .....	33
<u>DISCUSSION OF ECONOMIC LOSS (166.20(b)(4))</u> .....	38
<u>ESTIMATED REVENUES FOR THE SITE TO BE TREATED (166.20(B)(4) ii &amp; iii)</u> .....	52

**CONTACT PERSON(S) AND QUALIFIED EXPERTS(S) (166.20(a)(1))**

**(i) The Contact Person for matters relating to the administration of this exemption:**

Daniel A. Botts/Michael J. Aerts  
Florida Fruit & Vegetable Association  
800 Trafalgar Ct.; Suite 200  
Post Office Box 948153  
Maitland, FL 32794-8153  
Phone: (321) 214-5200  
Fax: (321) 214-0210  
[daniel.botts@ffva.com](mailto:daniel.botts@ffva.com)  
[mike.aerts@ffva.com](mailto:mike.aerts@ffva.com)

Charlie Clark, Environmental Admin.  
FL Dept. of Ag and Consumer Services  
Pesticide Registration Section  
3125 Conner Blvd. (Bldg. 6)  
Tallahassee, FL 32399-1650  
Phone: (850) 617-7940  
Fax: (850) 617-7949  
[charlie.clark@freshfromflorida.com](mailto:charlie.clark@freshfromflorida.com)

**(ii) The contact people for matters relating to the technical aspects of this exemption:**

For Florida, it has been agreed that questions relating to technical aspects in the field for this emergency exemption petition will work through the Florida Department of Agriculture and Consumer Services and the Emergency Response Team within EPA's OPP.

For other technical aspects related to this petition, the contact is:

Agrosource:  
Mark Trimmer  
Director; R&D  
AgroSource, Inc.  
9889 Wilkinson Road  
Mazomanie, WI 53560  
Mobile: 608-628-2654  
[Mark@TrimmerConsulting.com](mailto:Mark@TrimmerConsulting.com)

Nufarm:  
Bill Bewlay  
Director, Business Development  
Nufarm Americas, Inc.  
4020 Aerial Center Parkway, Suite 101  
Morrisville, NC 27560  
(919) 379-2506  
[bill.bewlay@us.nufarm.com](mailto:bill.bewlay@us.nufarm.com)

**DESCRIPTION OF PESTICIDE REQUESTED (166.20(a)(2))**

**a. Common Chemical Names (Active Ingredients):**

Streptomycin Sulfate, Oxytetracycline Hydrochloride and Oxytetracycline Calcium

**Trade Names and EPA Registration Numbers:**

**FireWall™ 50WP Fungicide/Bactericide**

EPA Registration Number: 80990-4

**FireLine™ 17WP Fungicide/Bactericide**

EPA Registration Number: 80990-1

**Mycoshield®**

EPA Registration Number: 55146-97

**Formulation:**

All products are Wettable Powders

**Percent Active Ingredient:**

**FireWall™ 50WP:** 65.8% Streptomycin Sulfate (equivalent to 50% streptomycin)

**FireLine™ 17WP:** 18.3% Oxytetracycline Hydrochloride (equivalent to 17% oxytetracycline)

**Mycoshield®:** 31.5% Oxytetracycline Calcium Complex (equivalent to 17% oxytetracycline)

**Manufacturers:**

FireWall™ and FireLine™: AgroSource, Inc.

Mycoshield®: Nufarm Americas, Inc.

b. Additional labeling: see Appendix D (FireLine™ and FireWall™) and Appendix E (Mycoshield®) for the proposed Section 18 labels.

**DESCRIPTION OF PROPOSED USE (166.20(a)(3))**

**(i) Site to be Treated:**

**Rationale for Multiple Active Ingredient Products:**

The Citrus Research and Development Foundation, Inc., (CRDF), a Florida based independent grower research support organization was created and funded by grower assessments to guide the search for solutions to the recently introduced disease/vector complex Huanglongbing disease/Asian citrus psyllid. This research effort has proceeded across many fronts, one of which is the discovery and development of therapeutic treatments for infected trees. This program has directly participated in the funding of

projects with registrants of agricultural antibiotics to determine the role if any these compounds may provide in addressing this industry need. These projects were initiated over the past twenty-four months and have provided indications of value in maintaining the health and productive vigor in citrus trees that are infected with the pathogen.

Initial experimentation and experience gained in commercial citrus groves with this disease/complex suggests that multiple bactericide applications will be necessary in order to improve tree health and suppress the effects of Huanglongbing (HLB) disease season-long/year-round on infected citrus trees. The information developed independently by the two registrants in cooperation with the Citrus Research and Development Foundation over the past two years indicates a measure of suppression and overall increase in tree health in HLB-infected citrus trees. Each registrant developed their research package independently of the other's involvement and the resulting data indicates the three products have efficacy when used in a season long program targeted to the flush periods in citrus. The use patterns of the oxytetracycline products, while somewhat complementary, were not based on the same treatment regimes. This petition has attempted to consolidate use patterns across those treatment regimens and develop a package that would allow the flexibility of the treatments proposed in each individual package. It is important to note that the research program to refine and finalize final use patterns are on-going and will result in label expansion actions by each registrant. It must be recognized that while all of these products have activity on other citrus plant pathogens, the reason for this petition is the need for a therapeutic treatment to prolong the life and viability of trees infected with HLB.

Additionally, the further rationale supporting the use of multiple active ingredients for this particular Section 18 request include the following:

- The *Candidatus Liberibacter asiaticus* (CLas) bacterium is a difficult organism to work with, starting with the fact that this organism has never been successfully cultured in the laboratory. Its potential to develop resistance to antibacterial compounds applied for its control in the field is therefore unknown.
- Since CLas may develop resistance if treated with just a single bactericide product, an effective resistance management strategy must be part of any antibacterial HLB management program from the start.
- The heart of any effective resistance management strategy against CLas will be the use of at least two bacterial control agents, each having a unique mode of action against the pathogen.
- Based on their respective and unique modes of action, streptomycin sulfate is classified as a Group 25 fungicide; oxytetracycline is classified as a Group 41 fungicide according to the Fungicide Resistance Action Committee (FRAC).

- The use of streptomycin and oxytetracycline in alternation will thus minimize any selection pressure on CLas for development of resistance to either streptomycin or oxytetracycline.
- Since both streptomycin and oxytetracycline are individually efficacious against CLas in HLB-infected citrus, attacking the situation with these multiple products in rotation constitutes an effective resistance management program for HLB management and tree health improvement, thereby ensuring the long-term efficacy of these products against the CLas pathogen.
- This resistance management program should also help in preventing development of resistance in non-target bacteria as well.

All citrus (statewide) is the site to be treated. The proposed crop spectrum to be treated is slightly different for the two formulations of oxytetracycline. The FireLine™ label and FireWall™ label covers all of the Citrus Crop Group 10, whereas the Mycoshield® label is proposing use on Orange, Crop Subgroup 10-10A and Grapefruit, Crop Subgroup 10-10C. According to the latest figures available from the 2015 Citrus Reference Book (Florida Agricultural Statistics Service Citrus Summary, 2013 – 2014; February 2015), in 2014 there was a total of 515,147 acres of Florida commercial citrus acreage (452,364 acres oranges, 45,922 acres grapefruit, and 16,861 acres specialty citrus). In a subsequent report (September 17, 2015), The National Agricultural Statistics Service reported 126,613 acres of abandoned or untended citrus acreage. This acreage would be deducted from the above number resulting in potentially treated acreage of 388,534 acres. See Appendix A for Florida counties and acreages in citrus.

**(ii) Method of Application:**

Ground application only.

**(iii) Rates of Application (in terms of a.i. and product):**

**FireWall™ 50WP**

0.45 pounds active ingredient (a.i.) per acre per application

0.69 pounds of formulated FireWall™ 50WP per acre per application

**FireLine™ 17WP**

0.27 pounds of active ingredient (a.i.) per acre per application

1.5 pounds of formulated FireLine™ 17WP per acre per application

**Mycoshield®**

0.255 pounds of active ingredient (a.i.) (oxytetracycline base) per acre per application

1.5 pounds of formulated Mycoshield® per acre per application

Rates of application for Mycoshield® are based on reaching a 200 ppm oxytetracycline (1.5 pounds of formulated product in 150 gallons of water)

concentration in a finished spray volume necessary to fully cover the foliage of the tree to be treated. Spray volume and use rates per acre can be scaled downward in smaller trees depending on the amounts of spray volume to provide full coverage.

**Maximum Number of Applications:**

**FireWall™ 50WP**

A maximum of 3 applications per year is proposed, totaling no more than 2.07 pounds of formulated FireWall™ 50WP per acre per year (1.35 pounds active ingredient).

Allow a minimum of 21 days between applications.

**Fireline™ 17WP**

A maximum of 3 applications of this formulation per year is proposed, totaling no more than 4.5 pounds of formulated FireLine™ 17WP per acre per year (0.81 pounds active ingredient).

Allow a minimum of 21 days between applications.

**Mycoshield®**

A maximum of 8 applications per year is proposed, totaling no more than 12 pounds of formulated Mycoshield® per acre per year (2.04 pounds oxytetracycline base). Mycoshield® would be labeled to suppress infections of HLB in foliage with applications beginning two weeks after the initiation of a new leaf flush. Closer spray intervals are conducive to better performance but limit the ability to use the product on multiple flushes. Wider spray intervals and fewer applications on a given flush may not be as effective but allows for more applications on successive flushes, especially in young small frame citrus trees.

**(iv) Total Acreage (or other units) to be Treated:**

During 2013-14, approximately 515,147 acres of citrus were grown in Florida. Of this acreage 388,534 acres remain under commercial management.

**(v) Total Amount of Pesticide to be Used (in terms of a.i. and product):**

**FireWall™ 50WP**

In an absolute worst-case scenario, 804,265 pounds of formulated FireWall™ 50WP Fungicide/Bactericide, or 695,448 pounds of streptomycin sulfate, would be needed. (388,534 acres X 0.69 pounds of formulated FireWall™ 50WP X 3 applications = 1,066,354 pounds FireWall™ 50WP Fungicide/Bactericide; 388,534 acres X 0.45 lbs. a.i. X 3 applications = 524,520 lbs. a.i. streptomycin sulfate).

### **FireLine™ 17WP**

At the maximum, 1,748,403 pounds of FireLine™ 17WP or 314,712 pounds of oxytetracycline hydrochloride, would be needed. (388,534 acres X 1.5 pounds of formulated FireLine™ 17WP X 3 applications = 1,748,403 pounds FireLine™ 17WP; 388,534 acres X 0.27 pounds a.i. X 3 applications = 314,712 pounds of oxytetracycline hydrochloride).

### **Mycoshield®**

The total amount of Mycoshield® that could be used under the specific exemption assuming all trees are treated the maximum number of recommended applications would be a total of 4,662,408 pounds of formulated Mycoshield® or 762,309 pounds of oxytetracycline calcium. (388,534 acres X 1.5 pounds of Mycoshield® X 8 applications = 4,662,408 pounds of Mycoshield®; 388,534 acres X 0.255 pounds oxytetracycline base X 8 applications = 762,309 pounds of oxytetracycline base). While the use of Mycoshield® is limited to citrus crop subgroups 10 A and 10 C, the members of crop subgroup 10B (limes and lemons) represent less than 2,000 acres of production in Florida (less than 2,550 lbs of active ingredient).

### **Note Oxytetracycline Formulations:**

Across the two formulations of oxytetracycline, the total amount of the active ingredient oxytetracycline that would be allowed under the proposed use patterns included in this petition is equivalent to the maximum amount of active ingredient that could be applied per individual acre of treated citrus under the proposed Mycoshield® Section 18 label plus the amount adjusted for the three applications on Citrus Subgroup B, which is allowed on the proposed FireLine™ 17 Section 18 label (0.81lbs X 2,000 Acres of lemons and limes = 1,620 lbs). This is (762,309 lbs. – (2,550 lbs. (5 applications at .255 lbs.)) = 759,759 lbs. of oxytetracycline. The use across the two formulated products (on Citrus Subgroups 10 A and 10 C) would be additive over the season and capped at the maximum level of active ingredient per acre of 2.04 lbs. of oxytetracycline for Citrus Subgroups A & C and 0.81lbs. on Citrus Subgroup B. We would encourage the Agency in their decision document to clearly state that the maximum amount of oxytetracycline per acre per season is capped so that if growers choose to use both products they do not exceed the maximum per acre use allowed.

While the amounts of product that could be needed is projected above; it is highly probable that not all of the eligible acreage will be treated, and a portion of the treated acreage will be treated at lower use rates than the maximum rate because of smaller canopy size in the younger age classes of

trees. This will result in less material being used than the numbers projected above.

(vi) **Use Season (period of time for which use of chemical is requested):**

Access would be needed by February 1, 2016, to coincide and overlap with the typical spring foliage flush emergence. Availability subsequent to the date of approval is requested and crucial over the ensuing 12 months, especially when considering the continued infection rates and subsequent tree losses resulting from HLB disease.

**FireWall™ 50WP**

FireWall™ 50WP will be applied to all varieties and cultivars included in the Citrus Crop Group 10. Make an initial application at initiation of spring flush to suppress HLB titer and disease symptoms. Make a second application mid-summer (not less than 21 days after first application). Make a third application in late summer to reduce the incidence of HLB-induced fruit drop and to further suppress HLB titer and disease symptoms (not less than 21 days after second application). Spray to near runoff. Applications of FireWall™ 50WP should be rotated with another bactericidal product having a different mode of action, to reduce risks of selecting for streptomycin-resistant organisms.

**FireLine™ 17WP**

FireLine™ 17WP will be applied to all varieties and cultivars included in the Citrus Crop Group 10. Make an initial application at initiation of spring flush to suppress HLB titer and disease symptoms. Make a second application mid-summer (not less than 21 days after first application). Make a third application in late summer to reduce the incidence of HLB-induced fruit drop and to further suppress HLB titer and disease symptoms (not less than 21 days after second application). Spray to near runoff.

**Mycoshield®**

The recommendation is to make 3 to 4 applications to growth flushes in the spring and fall. Applications to the spring flush could be initiated in February through April depending on the citrus variety and the severity of the winter. It may take until the end of May to complete the entire application program on the spring flush. Fall flushes would consist of periods of new growth initiating after September 1<sup>st</sup>.

Foliar applications of these antibiotics are not expected to cure systemic infections of HLB in the branches, trunks or roots of a diseased tree. Application flexibility is needed so growers can target periods of disease

suppression and relief of associated symptoms that best fit their overall production program.

**(vii) Additional Restrictions, User Precautions and Requirements, Qualifications of Applicators, etc.:**

All active ingredients will be applied in accordance with the proposed Section 18 label and all applicable provisions of the Section 3 registered labels. Examples of various restrictions, requirements and qualifications include but are not limited to:

**FireWall™ 50WP**

- A total of three (3) applications of FireWall™ 50WP may be made at no less than 21 day intervals.
- Do not apply at less than 40 days prior to harvest.
- Do not apply through irrigation systems or by aircraft.
- Do not apply more than 2.07 pounds of formulated FireWall™ 50WP (1.35 pounds active ingredient) per acre.
- Personal protective equipment for applicators and handlers includes:
  - Long sleeved shirt
  - Long pants
  - Chemical resistant gloves made of a waterproof material
  - Shoes plus socks
  - Protective eyewear
  - MSHA/NIOSH approved dust/mist respirator with any N, R, P or HE filter.
- Worker re-entry into treated areas during the restricted entry interval of 12 hours is not allowed. For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:
  - Coveralls over long-sleeved shirt and long pants
  - Chemical-resistant gloves made of a waterproof material
  - Shoes plus socks
  - Protective eyewear.
- Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark.
- Do not contaminate water by cleaning of equipment or disposal of equipment washwater.
- The FireWall™ 50WP label contains a CAUTION statement of hazard and this product is considered to be a "General Use" pesticide. As a non-restricted pesticide, farmers without private applicator certification,

farmers with private applicator certification, and licensed commercial applicators are allowed to apply FireWall™ 50WP.

### **FireLine™ 17WP**

- A total of three (3) applications of FireLine™ 17WP may be made at no less than 21 day intervals.
- Do not apply at less than 40 days prior to harvest.
- Do not apply through irrigation systems or by aircraft.
- Do not apply more than 4.5 pounds of formulated FireLine™ 17WP (0.81 pounds active ingredient) per acre.
- Personal protective equipment for applicators and handlers includes:
  - Long sleeved shirt and long pants
  - Chemical resistant gloves made of a waterproof material
  - Shoes plus socks
  - Protective eyewear
  - Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC -21C) or a NIOSH approved respirator with any N , R, P or HE filter.
- Worker re-entry into treated areas during the restricted entry interval of 12 hours is not allowed. For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:
  - Coveralls over long-sleeved shirt and long pants
  - Chemical-resistant gloves made of a waterproof material
  - Shoes plus socks
  - Protective eyewear.
- Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark.
- Do not contaminate water by cleaning of equipment or disposal of equipment washwater.
- The FireLine™ 17WP label contains a CAUTION statement of hazard and this product is considered to be a "General Use" pesticide. As a non-restricted pesticide, farmers without private applicator certification, farmers with private applicator certification, and licensed commercial applicators are allowed to apply FireLine™ 17WP.

### **Mycoshield®**

- A total of eight (8) applications of Mycoshield® may be made at no less than 21 day intervals.
- Do not apply at less than 21 days prior to harvest.
- Do not apply through irrigation systems or by aircraft.

- Do not apply more than 12.0 pounds of formulated Mycoshield® (2.04 pounds oxytetracycline base) per acre.
- Personal protective equipment for applicators and handlers includes:
  - Long sleeved shirt.
  - Long pants.
  - Chemical resistant gloves made of a waterproof material.
  - Shoes plus socks.
  - Protective eyewear.
- Dust/Mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, R, P or HE filter.
- Worker re-entry into treated areas during the restricted entry interval of 12 hours is not allowed. For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:
  - Coveralls over long-sleeved shirt and long pants
  - Chemical-resistant gloves made of a waterproof material
  - Shoes plus socks
  - Protective eyewear.
- Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark.
- Do not contaminate water by cleaning of equipment or disposal of equipment washwater.
- The Mycoshield® label contains a WARNING statement of hazard and this product is considered to be a "General Use" pesticide. As a non-restricted pesticide, farmers without private applicator certification, farmers with private applicator certification and licensed commercial applicators are allowed to apply Mycoshield®.

Other specific use directions to be followed are found on the proposed Section 18 labels and the Section 3 labels found in Appendices D and E.

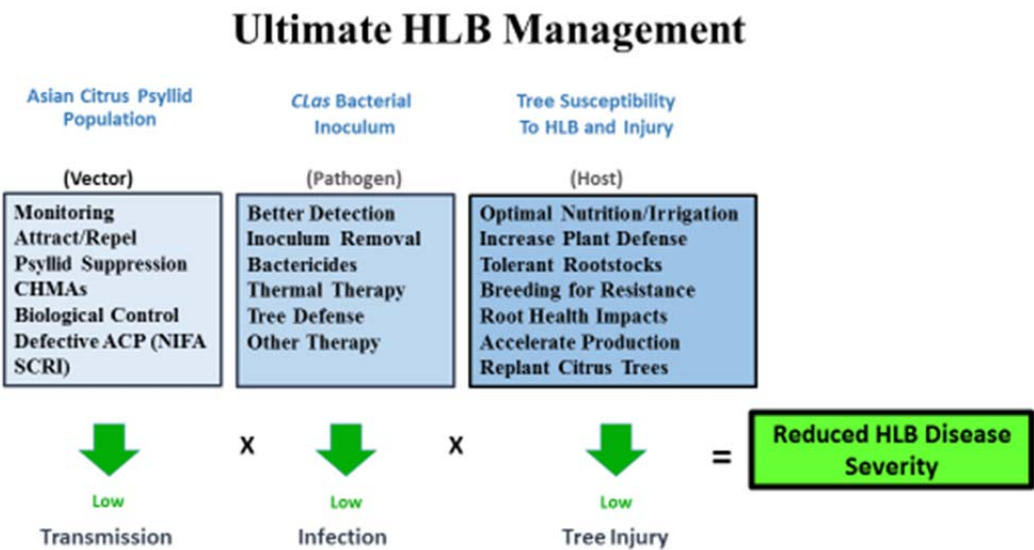
#### **ALTERNATIVE METHODS OF CONTROL (166.20(a)(4) ):**

##### **(i) Detailed Explanation of Why Currently Registered Pesticides Are Not Available in Adequate Supply and/or Are Not Effective to Control the Emergency:**

The Huanglongbing (HLB) disease/vector complex and its impact on the industry have been rapidly increasing since the disease was first identified in Florida in August of 2005. The fact that HLB was on the U.S. Department of Homeland Security's Select Agent List made field work next to impossible until that status was modified. As experience with the disease has progressed, it has become apparent that managing the disease at levels that

will allow continued commercial production in Florida depends on a multifaceted management strategy. This strategy includes the ability to replace non-productive trees with a realistic expectation that the newly planted replacement trees will have a reasonably productive life. Even with the complexities created by the lack of ability to culture the bacteria outside of the citrus vascular system and the digestive system of the insect, the industry has made significant strides in identifying the critical components of this management process.

From the beginning, there have been a range of approaches attempted to manage the devastation that HLB has caused to Florida citrus, and the pursuit of many parallel strategies continues. Challenges of managing HLB disease in Florida citrus are many and the application of tools that are available and emerging from research have yet to provide for a sustained leveling of disease impact or to restore tree health and productivity to trees infected with the pathogen. The graphic below highlights the breadth of effort underway in research to discover, test and deliver solutions to HLB, identifying the primary targets for intervention. Vector control, combined with therapy to reduce *CLas* titers (bacterial concentrations) in infected trees and ultimately, deployment of resistant or tolerant plant materials offers the balanced approach to disease management. Because of the absence of effective tools for bacterial therapy (the basis for this petition) and no proven plant resistance, the disease continues to impact all Florida growers and is discouraging the much-needed replanting to complement the current struggling tree inventory.



From the outset, it has been clear that vector control was tantamount to slow the spread of the disease, and many strategies were advanced to achieve this goal. Insecticidal suppression, biological control, attractants and repellants and other approaches have

been pursued, and as a result, Asian citrus psyllid (ACP) populations are well below initial levels. Similarly, as CLas infection spread and the numbers of infected trees grew, expansion of ACP control was necessary to protect new plants in existing groves and new plantings from becoming infected. Soil-applied neonicotinoid insecticides play a major role in protecting young trees during critical periods as they grow through the first 5 years, and these insecticides become more important as the disease reservoirs of inoculum and vector populations continue to expand. ACP suppression remains a critical component of HLB management with research and grower experience continuing to demonstrate the value of this segment of HLB management.

Florida citrus growers realized early that sustaining plant health through horticultural practices was an important response to onset and advancement of HLB disease. While trees possess considerable resilience in response to stresses, a chronically declining tree loses much of its resilience, and therefore must be managed more carefully. “Just-in-time inputs” or “spoon-feeding” trees showing advanced HLB symptoms with irrigation and fertilization can dampen limitations of compromised root systems, and cultural practices have been modified to more intensively manage tree health. In addition, plant growth regulators are being evaluated and used in an effort to assist in phloem regeneration and to limit pre-harvest fruit drop associated with HLB decline. Other cultural practices are being investigated to sustain health and productivity of infected trees and perhaps prolong productive life of these trees. Some of these same practices of intensive management are likewise being applied to newly planted trees to meet the goal of accelerating tree growth and maturity, thereby allowing for economic return to growers before HLB-induced tree decline commences. However, consistent success in this effort remains elusive.

Neither vector suppression nor cultural practices directly impact the bacterial pathogen, CLas, which is the target of the intervention proposed in this petition.

The goal of reducing CLas titer in infected trees has proven quite challenging, and relatively little progress has been made in this arena. The location of the pathogen within the plant’s vascular system, difficulty of early detection of infection in citrus plants, and the inability of researchers to work with cultures of the bacteria CLas have limited development of CLas therapies to two strategies.

The first of these strategies is application of thermal therapy, where external heat is applied actively or passively to infected trees to differentially cause bacterial mortality in phloem tissues, while not harming the host plant tissues. The differential time versus temperature requirements to achieve this goal are being pursued through research and field experimentation on commercial farms.

The alternative to thermal therapy is the application of chemical therapy, wherein bactericidal chemicals are applied to trees to reduce CLas bacterial titer. This approach has been a priority focus for industry research efforts and extensive investment in evaluating efficacy, dose response, phytotoxicity and other parameters important to

development of a therapy tool. Chemical therapy encompasses a range of chemistries that correspond to various regulatory pathways, from conventional agricultural antibiotics to biopesticides to new active ingredients. Chemistries that fall within currently registered pesticides, 25(b) exempt list, or biopesticides offer the shorter term opportunities and these are being pursued aggressively while longer term new active ingredients are developed. Our strategy has focused most aggressively on agricultural antibiotics as these products offer an opportunity for label expansion from other U.S. crop uses as bactericides, and for which there is a broad pool of supporting data.

Processes in place to evaluate chemical therapy candidates include:

- A comprehensive laboratory bioassay system progressing from a high throughput surrogate bacterial assay to whole plant greenhouse assays;
- A range of field research spanning single plant initial trials to large scale commercial trials conducted in concert with registrants;
- Efficacy as a function of a.i., dose, timing, application method and disease intensity has been evaluated, as well as phytotoxicity, movement within the plant, and residues in plant parts.

Finally, several long-term lines of technology are being developed to identify and move the genetic components necessary to convey resistance into horticulturally important citrus cultivars. Field trials have been initiated to further investigate the potential for this to serve as a long-term means of restoring the viability of the industry. But, results are still expected to be years off.

All of this work in the state of Florida is being coordinated through the Citrus Research and Development Foundation (CRDF). This program of research to develop and deliver HLB solutions is also coordinated with existing national and international programs through USDA ARS, other research institutions, and, industry associations in Texas and California.

## **(ii) Alternative Control Practices:**

Alternative CLas therapy/suppression practices are outlined above and are restricted at present to thermal therapy and chemical therapy. While there are other approaches mentioned above for vector or plant health management, none of these address reducing CLas titer in infected trees, and these tools are not likely to affect decline of infected trees.

### **Thermal therapy:**

Some success has been observed with application of passive solar energy or active steam heat to young trees. These field demonstrations and trials have been evolving since the

spring of 2014, when proof of concept was completed with solarization inside single-tree tents. Early attempts with both passive and active thermal treatment resulted in severe tree injury or actual tree death, leading to subsequent investigations to define time/temperature relationships and methods of delivery to achieve the differential thermal effects on bacteria while preventing tree injury. At present, all systems operating in the field to advance this approach are designed to treat individual trees up to a maximum height of about 3 meters. Results appear most predictable when trees are in early stage in infection and disease onset. While delivery systems and time/temperature characteristics are being resolved, predictability of response and expected duration of effects are in early stages of evaluation. Practical limitations of the number of trees that can be treated with thermal therapy and the expected outcomes in balancing bacterial titer reduction with increasing injury to leaves, limbs and fruit on treated trees are being evaluated in small-scale field trials in Florida. Research and commercialization funding is encouraging innovation to solve issues of practical application of this CLas suppression strategy, but progress is slow at present. It is anticipated that this approach will emerge on a commercial scale as a tool for managing early infection that will perhaps be limited to young (small) trees.

### **Chemical Therapy of CLas:**

Chemical therapy of CLas is under intensive investigation in Florida citrus, with relatively few candidate materials advanced to commercial use or demonstrated effectiveness. The only antibiotics available for use in the agricultural sector include streptomycin, oxytetracycline and kasugamycin. Among the groups of chemistries under consideration, the bactericides labelled for use in other crops are the front-runners in terms of available data and performance testing in Florida citrus. These are the subjects for this Emergency Exemption petition.

Alternatives available for field use against CLas are few. CLas bioassay and field trials are being conducted on the biopesticides that are labelled for pest or disease control in citrus to determine how effective these materials might be under current field use patterns. Field research is ongoing, but results that could indicate a clear effect are not yet available. Optimism around these products exists but none of these materials are currently considered as demonstrable CLas therapy.

Other alternative chemistries that are being evaluated in Florida citrus for HLB suppression or tree health management include products based on plant essential oils. Some of these oils appear on the EPA 25(b) exempt list. Several products containing plant essential oils are available in Florida [e.g., Thymeguard (AgroResearch), and Ecotrol Plus (Keyplex®)]. These products are being field evaluated by growers to determine their impact on HLB through foliar application.

Field trials are underway to quantify the impact of these potential tools, but it is too early to have meaningful results. Similarly, field evaluations by Florida growers in conventional and organic citrus blocks have failed to demonstrate a measurable effect of these plant

essential oils. While these tools may complement the bactericides being considered in this petition, there is limited evidence for their effectiveness in reversing HLB.

### **EFFECTIVENESS OF USE PROPOSED UNDER SECTION 18 (166.20(a)(5))** **(166.20(a)(5))**

#### **FireWall™ 50WP and FireLine™ 17WP**

To assess the potential management of HLB disease, foliar applications of two bactericides, streptomycin sulfate and oxytetracycline hydrochloride were applied to commercially-grown grapefruit and oranges at 17 Florida field test locations in 2014 (year 1) and 2015 (year 2). Trials were located in the Indian River, the Central Ridge and the Peace River regions of Florida's citrus industry. Prior to treatment applications, all trees at each location were confirmed to test "positive" for HLB, based on PCR (polymerase chain reaction) analysis. Treatment effects for streptomycin and oxytetracycline applications were determined by quarterly DNA titer assays of the bacterium *Candidatus Liberibacter asiaticus* present in leaf samples collected from each treatment plot. In addition, multiple assessments of tree health were made, including improvement in tree canopy density (e.g. health), increased tree height and reductions in leaf drop, fruit drop, visual HLB symptoms, branch dieback and increases in fruit load in treated versus untreated trees. Foliar applications with streptomycin or oxytetracycline to grapefruit and orange trees in year-1 resulted in a statistically significant reduction ( $p < 0.05$ ) in *CLas* titer, and this remained evident 4 to 5 months after the last application of streptomycin or oxytetracycline. In addition, significant improvements ( $p < 0.05$ ) in leaf drop, fruit drop, visual HLB symptoms, and visual tree health, were noted in treated year-1 trees. Significant treatment effects ( $p < 0.05$ ) were also recorded for these same parameters plus tree height in year-2. Results from these trials showed that foliar applications of streptomycin and oxytetracycline bactericides to commercially grown citrus significantly reduces titer for *CLas* in HLB-infected trees, and results in significant improvements to overall tree health. These field evaluations serve to illustrate that the reduction in *CLas* titer from the PCR results has correlation to healthier citrus trees in a production grove environment.

#### **Mycoshield®**

Mycoshield® oxytetracycline calcium complex was first registered in 1979 for control of fire blight (*Erwinia amylovora*) of pear and bacterial spot (*Xanthomonas arboricola* pv. *pruni*) of peach. Apple (fire blight) and nectarine (bacterial spot) were added to the label in later years. Oxytetracycline hydrochloride was first approved for agricultural use in 2004. EPA has determined that oxytetracycline calcium complex and oxytetracycline hydrochloride rapidly convert to oxytetracycline when added to water and "both OTC calcium complex and OTC-HCL will be mainly introduced into the environment as OTC." Thus, it was determined that environmental fate data for OTC calcium complex and OTC-

HCL are interchangeable. Disease control with the two forms is expected to be equivalent because the spray deposits would be oxytetracycline.

Oxytetracycline is produced naturally by *Streptomyces rimosus*. Commercial production of Mycoshield® is achieved by [REDACTED]. This is followed by an [REDACTED] that is used to make the final end product. OTC is a reversible bacteriostat that inhibits protein synthesis at the ribosome. Susceptible bacteria may resume development if the exposure period is inadequate for action by a secondary mortality factor such as senescence, attempted cell division, environmental stress or a host plant response.

Potted seedlings of various citrus cultivars were sprayed to run off with daily foliar applications of oxytetracycline at 100 ppm in a 1975 report (A. L. Martinez, 1975). A majority of the plants demonstrated partial recovery with obvious improvements in color and shoot production. However, none of the plants were completely cured. Injections of tetracycline to Sakkan orange and Fuyu mandarin at 500 to 1000 ppm were effective at reducing disease symptoms and preserving higher yields in a 1991 article (K. Chung and W. Zhisheng, 1991). The trees were not cured and growth of the disease was evident one year later. Injection of tetracycline resulted in phytotoxic effects such as rotten tissue around the injection points and leaf drop. Oxytetracycline was not considered to be of value in the early stages of the Florida epidemic because of the inability to cure infected trees.

The following characteristics are required for bactericides to make definitive claims for direct suppressive activity on HLB and have practical utility for use in the field:

1. **Proven activity on *Liberibacter spp.* in culture.** It must inhibit *Candidatus Liberibacter crescens*, the closest cultured relative of *Candidatus Liberibacter asiaticus*, at low concentrations. Oxytetracycline strongly inhibits *Candidatus Liberibacter crescens* culture growth by more than 90 percent at a concentration of 0.54  $\mu$ M, a level suitable for field use. Thus, it is believed that oxytetracycline can inhibit *Candidatus Liberibacter asiaticus*.
2. **Phloem mobility.** The chemical structure of oxytetracycline suggests that it can penetrate the phloem where the causal agent, *Candidatus Liberibacter asiaticus*, resides in the tree.
3. **Excellent crop safety.** Mycoshield® applied twice weekly to citrus at 1000 ppm for 12 weeks (24 total applications) did not cause noticeable injury in a 2013 field trial by the University of Florida's Dr. Eric Triplett (personal communication).

Zebra chip disease is caused by *Candidatus Liberibacter solanacearum*, a very close relative of *Candidatus Liberibacter asiaticus*. As in HLB disease, the *Liberibacter* pathogen resides in the phloem after having been vectored by a phloem-feeding insect (potato psyllid). Testing bactericides against zebra chip disease on tomato or potato generates

results much faster than can be obtained on citrus. Symptoms on tomato appear in 10 days but can take many months on citrus. Disease suppression through the use of an effective bactericide can be observed in less than three weeks in tomato but can take many months on citrus.

Zebra chip is not endemic to Florida, but laboratory and field research can be conducted in south Texas where the disease and potato psyllid are widely established. Dr. Erik Mirkov (Texas A&M AgriLife Research) has shown in laboratory studies that oxytetracycline effectively manages the symptoms of Zebra chip disease on tomato and dramatically reduces the number of bacteria residing in the plant (data in preparation for publication). Dr. Manuel Campos (Texas A&M AgriLife Research) conducted a field trial on potato in 2015. Five weekly applications of Mycoshield® at 200 ppm resulted in 13 percent infected tubers as compared to 90 percent in the untreated. This study demonstrated that oxytetracycline can reduce disease caused by a phloem-limited pathogen very closely related to *Candidatus Liberbacter asiaticus*.

Nufarm conducted experimental field trials in 2014 and 2015 (Better Crops, LLC, 2014 / 2015) evaluating the suppressive activity of Mycoshield® foliar sprays against HLB in Florida groves with HLB symptoms. This was a commercial grapefruit grove with 7 – 10 year old trees.

In 2014, the treatment list was based on anecdotal information suggesting that a combination of a bactericide with a strong penetrant (Pentra-Bark®) plus fertilizers would provide the best results. Unfortunately, the treatments with Pentra-Bark®/fertilizer combinations (with or without a bactericide) resulted in phytotoxic effects in the form of severe leaf and fruit drop. Although 2014 growth information was confounded by the crop injury, qPCR data demonstrated that oxytetracycline foliar applications suppressed the incidence of HLB infection in new growth. Samples of mature foliage collected prior to the initiation of the program revealed an infection incidence of 75 – 100 percent throughout the study area. Samples of mature foliage collected after the treatment program (4 applications at 3 week intervals) had the same incidence of infection.

However, samples of new foliage that was flushing during the treatment period showed that all Mycoshield® foliar treatments (treatments 6 – 12) only had an infection incidence of 25 – 50 percent. The untreated, fertilizer + Pentra-Bark® alone, Agri-Mycin® 17 streptomycin (with and without Pentra-Bark®) and Mycoshield® trunk spray had an infection incidence of 50 – 75 percent.

**Table 1: Mycoshield® HLB Foliar Suppression - Grapefruit - St. Lucie W 2014**  
**Percent of Plots Positive for HLB / Old vs. New Foliage**

Treatment	% Old Infect 7-27	% Old Infect 10-29	% New Infect 10-29
Untreated	75	75	75
Fertilizer (F) + Pentra-Bark® (P)	75	75	50
Agri-Mycin® Low Vol (AL)	100	100	50
AL + P	100	100	75
Mycoshield® + P Trunk	75	75	50
Mycoshield® Low Vol (ML)	100	100	25
ML + P	75	75	50
Mycoshield® High Vol (MH) + P	75	75	25
ML + F + P	100	100	25
MH + F + P	100	100	25
MH + RTREX Plus	100	100	25
MH + KeyPlex® 1400 DP	100	100	25

Antibiotic Foliar and Trunk Applications: 7-27, 8-15, 9-12, 10-11

Fertilizer Foliar Application: 7-27, 9-12

Fertilizer: 1 gal chelated iron + 5 lb. zinc sulfate + 5 lb. manganese sulfate / A

Agri-Mycin® 17 and Mycoshield® Low Vol: 1.5 lb. product in 100 GPA

Mycoshield® High Vol: 1.5 lb. product in 150 GPA

Mycoshield® Trunk: 1.5 lb. in 12.5 GPA @ approximately 8 oz./tree

Pentra-Bark®: Applied at 0.5% v/v foliar; 2.5% v/v trunk

Infection Incidence: % of plots testing positive for HLB based on PCR of old or young foliage

**Table 2: Mycoshield® HLB Foliar Suppression - Grapefruit - St. Lucie W 2014**  
**Percent of Tree Canopy a Contiguous Leaf Wall**

Treatment	% leaf Wall Area 3-31-2015
Untreated	49 b
Fertilizer (F) + Pentra-Bark® (P)	48 b
Agri-Mycin® Low Vol (AL)	53 ab
AL + P	67 a
Mycoshield® + P Trunk	59 ab
Mycoshield® Low Vol (ML)	69 a
ML + P	67 a
Mycoshield® High Vol (MH) + P	71 a
ML + F + P	63 ab
MH + F + P	64 ab
MH + RTREX Plus	58 ab
MH + KeyPlex® 1400 DP	58 ab

Percent Leaf Wall: Visual assessment of canopy fullness averaged for 4 angles of perspective on each tree.

The 2014 study area recovered from the phytotoxicity and increased spring growth of the new canopy in 2015 was evident in all oxytetracycline foliar treatments relative to the untreated (9 – 22% denser canopy than the untreated). Several of the treatments were significantly superior to the untreated (5% probability level).

**Table 3: Mycoshield® HLB Foliar Suppression /Grapefruit - St. Lucie W 2015**

Treatment	Vigor Rating 7-21-2015
Untreated	5.2 c
Mycoshield® + Pentra-Bark® Trunk	5.5 bc
Phostrol® 4.5pt/100 gal	5.5 bc
Mycoshield® LV	5.6 bc
Mycoshield® HV	6.8 abc
Mycoshield® + Phostrol® LV	6.3 abc
Mycoshield® + Tactic® 0.125% LV	6.7 abc
Mycoshield® + Tactic® 0.125% HV	6.2 abc
Mycoshield® + Tactic® 0.125% LV 4 appl*	6.8 abc
Mycoshield® + Dyne-Amic® 0.25% LV	5.7 bc
Mycoshield® + Dyne-Amic® 0.25% HV	6.2 abc
Mycoshield® + LI 700 0.25% LV	7.1 ab
Mycoshield® + LI 700 0.25% LV	7.7 a

Three applications to spring 2015 flush @ 2 week intervals

\* A 4<sup>th</sup> application made 6 days after the 3<sup>rd</sup>

Mycoshield® Low Vol: 1.0 lb. product in 100 GPA

Phostrol® Low Vol: 4.5 pints in 100 GPA

Mycoshield® High Vol: 1.5 lb. product in 150 GPA

Mycoshield® Trunk: 1.5 lb. in 12.5 GPA @ approximately 8 ounces per tree

Pentra-Bark®: Applied at 0.5% v/v foliar; 2.5% v/v trunk

Tree Vigor Rating: 0 = dead; 10 = completely healthy growth

The 2015 grapefruit study was established on different trees. Application timing focused on periods of new growth flush in the spring, summer and fall. Periods of new growth are the optimal times for infection by CLas and it was expected that phloem penetration of oxytetracycline would occur at a greater concentration in newer foliage.

Many of the treatments involved the identification of additives that would improve performance without causing crop injury and the comparison of two spray volumes (100 and 150 gal/acre). Most treatments involved three applications at two week intervals initiated at a flush of new growth. Approximately six weeks after flush initiation, the foliage hardens, becomes less attractive to psyllid feeding and is less amenable to the penetration of oxytetracycline. One tank mix treatment of Mycoshield® + Tactic included a fourth spray applied six days after the third application. A trunk spray of Mycoshield® + Pentra-Bark® was added as a comparison with the foliar sprays which were applied to the point of runoff. Mid-season tree vigor ratings (0 – 10 scale) showed that all oxytetracycline foliar treatments were numerically higher than the untreated, trunk spray and Phostrol® alone. The mixture of Mycoshield® + LI 700 at 100 and 150 gal/acre was significantly superior to the untreated (5% probability level). Oxytetracycline degrades quicker at a neutral pH than under acidic conditions. LI 700 is an acidifying penetrating surfactant which may be stabilizing the applied residues and extending the period for leaf absorption.

Leaves were collected from selected treatments in the 2015 grapefruit trial and forwarded to Dr. Xiaolan Sun (Florida Department of Agriculture and Consumer Services,

Division of Plant Industry) for residue analysis. Dr. Sun uses a method that has a lower limit of quantification (1 ppm). Values lower than this may represent false detects. The analysis proved that oxytetracycline penetrated the foliage and was still detectable in the single treatment that was collected four days after application. As predicted the residues were higher in young leaves than old leaves. However, oxytetracycline was not found at the limit of quantification in leaves at 10 days after application. The grapefruit leaf residue analysis supports that the application needs to be less than 10 days to prevent HLB bacteria from recovering and resuming growth.

**Table 4: Mycoshield® - Grapefruit Leaf Residues 2015**

Treatment	Additive	# Appl	Last Appl	Sampled	Foliage Residues (ppm)	
					Mature	New
Untreated	none	0	NA	22 May	ND – all Reps	ND, 0.5
Mycoshield® Foliar 1.0 lb./100 GPA	none	3	12 May	22 May	ND – all Reps	ND, 0.5
Mycoshield® Foliar 1.5 lb./100 GPA	none	3	12 May	22 May	ND – all Reps	ND, 0.7
Phostrol® Foliar 4.5 pt./100 GPA	none	3	12 May	22 May	ND – all Reps	ND – all Reps
Mycoshield® + Phostrol® /100 GPA	none	3	12 May	22 May	ND – all Reps	ND – all Reps
Mycoshield® Foliar 1.0 lb./100 GPA	Tactic	3	12 May	22 May	ND – all Reps	ND – all Reps
Mycoshield® Foliar 1.0 lb./100 GPA	Tactic	4	18 May	22 May	1.4 ,0.9, 0.6, 0.8	2.9, 0.8, 1.6, 0.8
Mycoshield® Foliar 1.0 lb./100 GPA	LI 700	3	12 May	22 May	ND – all Reps	ND – all Reps
Mycoshield® Foliar 1.0 lb./100 GPA	Dyne-Amic®	3	12 May	22 May	ND – all Reps	ND – all Reps

Comparison of oxytetracycline residues in mature and new flush foliage collected from the same trees.

Residues determined by *Bacillus subtilis* bioassay.

Leaf samples collected by John Curtis, Better Crops, LLC.

Leaf analysis conducted by Dr. Xiaoan Sun, FDACS, Div. of Plant Industry.

**Table 5: Mycoshield® - Orange Leaf Residues 2015**

Treatment	Additive	# Appl	Last Appl	Sampled	Foliage Residues (ppm)	
					Mature	New
Untreated	none	0	NA	19 Aug	ND	ND
Untreated	none	0	NA	22 Aug	ND	ND
Mycoshield® Foliar 1.5 lb./150 GPA	none	1	18 Aug	19 Aug	3.2	7.3
Mycoshield® Foliar 1.5 lb./150 GPA	none	1	18 Aug	22Aug	ND	ND

Comparison of oxytetracycline residues in mature and new flush foliage collected from the same trees.

Residues determined by *Bacillus subtilis* bioassay.

Leaf samples collected by Henry Younce, KAC Agricultural Research, Inc.

Leaf analysis conducted by Dr. Xiaoan Sun, Florida Department of Agriculture and Consumer Services, Div. of Plant Industry

Similar results were obtained from a residue analysis of treated orange (Hamlin) foliage from another location. One day after application, the oxytetracycline residue concentration in new flush foliage was 7.3 ppm, which exceeded the concentration in mature leaves by more than 2X. At the orange site, residues were not detected in foliage at four days after application

Based on this information then, the following use instructions are proposed for the specific exemption:

- A use concentration of 200 ppm that provides disease suppression in field trials and is consistent with the current maximum use concentration on the Mycoshield<sup>®</sup> label.
- Full coverage foliar application to the point of run-off. Oxytetracycline residues are rapidly degraded and inactivated in the soil. High volume applications that result in the run-off of excess material would be of no performance value.
- Testing the crop safety of tank mixtures to avoid potential phytotoxicity issues.
- Targeting applications to periods of new leaf flushes. This is supported by disease suppression results, leaf residue analysis and the infection properties of HLB.
- Apply at 21 day intervals. Although there were distinct benefits with 2- and 3-week intervals in 2014 and 2015 field trials, there was room for improvement. As a bacteriostat, the activity of oxytetracycline is improved by extended intervals of exposure. Residues were not detected in foliage at 10 days after application in the grapefruit trial and at four days after application in the orange trial. Applications at 3 – 7 day can be made for labeled use for control of fire blight on apples and pears.
- Use in combination with an Asian citrus psyllid management programs recommended by local experts. Imperfect vector control and suppression of HLB would be complementary strategies.
- Studies (Xia, 2012) have shown that high summer temperatures reduce the HLB levels in infected trees and in the psyllid. Thus, this emergency exemption request recommends targeting spring and fall flushes with oxytetracycline applications when the greatest benefit is expected. The exception would be a grower that intends to use oxytetracycline in combination with vector control to delay the infection of newly planted trees. In this situation, all flushes would need to be targeted with both technologies. Additional research is needed to investigate the use of oxytetracycline in a preventative program and large treatment areas are needed to optimize the activity of the vector control component. The expanded treatment acreage allowed under this emergency exemption request will enable the investigation of large area HLB prevention programs.

## **DISCUSSION OF RESIDUES IN FOOD (166.20(a)(6)) (166.20(a)(6))**

### **FireWall<sup>™</sup> 50WP and FireLine<sup>™</sup> 17WP**

AgroSource, Inc. and the IR-4 Project have performed Magnitude of Residue studies for streptomycin sulfate and oxytetracycline in/on citrus commodities. Field residue studies have been conducted and this information has been submitted to the Agency or is being

submitted to the Agency. Dietary and drinking water exposure and risk assessment with the current crop uses plus citrus have been performed using DEEM-FCID version 4.02 and citrus residue data from recent citrus field studies treated with three foliar applications at the proposed Section 18 label rates of both streptomycin and oxytetracycline each application. Based on available information, a temporary streptomycin tolerance of 0.5 ppm and a temporary oxytetracycline tolerance of 0.1 ppm on citrus are proposed.

For the streptomycin dried pulp fraction, the proposed tolerance will be 3.5 ppm and for the oil and juice fractions the proposed tolerance is 0.005 ppm (50% of the LOQ).

For oxytetracycline, no residues (LOQ=0.01 ppm) were found in whole fruit, orange peel, juice or dried pulp in crop residue trials. Residues of oxytetracycline in orange oil ranged from ND (<0.002 ppm) to <LOQ (0.01 ppm). Therefore, the NAFTA MRL of 0.01 ppm on the citrus fruit group 10-10 is proposed as the tolerance.

The summary of the residue data and the corresponding risk assessments to support the use of FireWall™ and FireLine™ for on citrus is included in the Appendix D – 3 and D – 4)

### **Mycoshield®**

A GLP residue study on citrus fruit sponsored by Nufarm Americas Inc. was initiated in March 2015 to support a tolerance petition and registration application for the use of Mycoshield® on the Citrus Fruit Crop Group 10-10 commodities. The study is expected to be completed by the end of June 2016. Residue data are currently available for several of the field trials and include data for raw agricultural commodities and processed fractions. Based on available data, Nufarm is proposing the establishment of time-limited tolerances for residues of oxytetracycline in or on orange, Crop Subgroup 10-10A, at 0.4 ppm and grapefruit, Crop Subgroup 10-10C, at 0.4 ppm. A summary of analytical results is provided in the Appendix E - 3.

The proposed time-limited tolerances for orange and grapefruit commodities are consistent with the tolerances of 0.35 ppm already established for apples, pears and peaches. The processing study was conducted at the exaggerated rate of 5 times the proposed application rate of 1.5 pounds Mycoshield®/acre (7.5 lb. Mycoshield®/acre). No detectable residues were found in orange juice. Residues in whole oranges and grapefruit were approximately 0.2 and 0.02 ppm, respectively.

To mitigate the small dietary risk posed by the specific exemption use on Florida orange and grapefruit crop subgroups 10-10A and 10-10C, a maximum of 8 applications per year and a maximum annual rate of 12 pounds of Mycoshield® per acre are proposed (compared to the 12 applications and the total rate of 21 pounds of Mycoshield® per acre used for the conduct of the residue study on citrus). In addition, a retreatment interval of 21 days is proposed instead of the 2-day retreatment interval used in the residue

trials. With these risk mitigation measures in place, it is very unlikely that any residues detected in treated citrus commodities will exceed the proposed time-limited tolerances for oxytetracycline in/on orange and grapefruit crop subgroups 10-10A and 10-10C. The incremental risk associated with the Section 18 use is therefore expected to be below the Agency's level of concern.

The summary of the residue data and the corresponding risk assessments to support the use of Mycoshield on citrus subgroup 10(A) and 10(C) is included in the Appendix E – 3 and E – 4)

### **Proposed Time Limited Tolerance**

It is anticipated that a single time limited tolerance would be set for the use of Oxytetracycline under the Section 18. As a result of the status of the supporting data across both registrants we would propose the following:

- Fruit, citrus, subgroup 10-10A at 0.4 ppm (the highest of the tolerance level needed for both FireLine 17WP and Mycoshield)
- Fruit, citrus, subgroup 10-10B at 0.1 ppm (needed to cover anticipated residues resulting from the use of FireLine 17WP only)
- Fruit, citrus, subgroup 10-10C at 0.4 ppm (the highest of the tolerance level needed for both FireLine 17WP and Mycoshield)

### **DISCUSSION OF RISK INFORMATION (166.20(a)(7))**

**Description of application sites, including proximity to residential areas, aquatic systems, endangered or threatened species habitats, soil types, etc.:**

#### **FireWall™ 50WP and FireLine™ 17WP**

FireWall™ 50WP and FireLine™ 17WP will only be applied to commercial citrus groves. These groves are typical of those found in Florida. Commercial groves are intensive and no unreasonable risks to human health, endangered or threatened species, beneficial organisms, or the environment are expected from the proposed use of this product.

Also included in the Appendix is an executive summary of work done in association with FDA requirements #152, Resistance Risk Assessment for Foliar Applications of FireWall™ and FireLine™ to citrus crops. With integration of the effective resistance management options, this situation does not significantly change the existing Qualitative Risk Assessment for the emergence of streptomycin or oxytetracycline resistance among clinical pathogenic bacteria. Since this proposed new use of streptomycin and oxytetracycline on citrus crops to improve tree health

and manage HLB is unlikely to represent a source for potential emergence of streptomycin or oxytetracycline resistance among clinical pathogens, approval of the proposed new use of streptomycin and oxytetracycline on citrus crops is believed to be in the public interest.

### **Mycoshield®**

Mycoshield® will be applied to commercial orange and grapefruit plantings, including all citrus fruit belonging to the citrus crop subgroups 10-10A and 10-10C (Calamondin; citron; citrus hybrids; grapefruit; Japanese summer grapefruit; Mediterranean mandarin; orange (sour); orange (sweet); pummelo; satsuma mandarin; tachibana orange; tangelo; tangerine (mandarin); tangor; trifoliate orange; uni fruit; cultivars, varieties, and/or hybrids of these). Use under the Section 18 will occur in all areas of the state with commercial citrus groves.

### **Possible risks posed by use:**

#### **FireWall™ 50WP and FireLine™ 17WP**

FireWall™ 50WP Fungicide/Bactericide and FireLine™ 17WP Fungicide/Bactericide are approved products registered by the U.S. Environmental Protection Agency that have been used in the field for more than 40 years. Possible risks were evaluated during Section 3 registration and reregistration processes for both compounds. FireWall™ is currently registered for use on crops such as beans, celery, peppers, potatoes, tomatoes, apples and pears, and FireLine™ is currently registered for use on crops such as apples, pears, peaches and nectarines. No unreasonable adverse effects to man or the environment are anticipated with this proposed use of three applications of streptomycin and three applications of oxytetracycline to Florida citrus. Additional information for FireWall™ and FireLine™ on these subjects can be obtained from Taw Richardson with AgroSource. His phone number is (908) 215-3500.

Facts associated with the potential for increasing the risk of human resistance to streptomycin and oxytetracycline have also been addressed in the TRED for oxytetracycline and the R.E.D. Facts publications for streptomycin, streptomycin sulfate and oxytetracycline. The streptomycin R.E.D. EPA report says that "regarding the problem of drug resistance, EPA has no data indicating that streptomycin residues remaining in the food supply have a significant or even a measurable potential for increasing human resistance to that drug." The Regulatory Conclusion of that same publication says that "all currently registered pesticide products containing streptomycin or streptomycin sulfate as the active ingredient are not likely to cause unreasonable adverse effects in people or the environment." The TRED for streptomycin says that "antibiotic resistance from pesticidal use of streptomycin is unlikely to result directly from dietary residues of streptomycin because dietary residues are very low. The drug dose is 3,000 times greater than the estimated pesticidal dietary exposure. The small dose from

(streptomycin) pesticidal exposure would not be expected to select for resistant bacteria because very few bacteria would be killed by this small dose.”

The streptomycin FDA #152 study summary paper notes that “streptomycin has been safely and effectively used in plant agriculture since 1955, yet a direct connection to the emergence of streptomycin resistance among clinical pathogens as a consequence of this use pattern remains undocumented. EPA has previously determined that the dietary exposure to streptomycin is below its level of concern. The use of streptomycin to manage HLB in commercially grown citrus crops does not increase the chronic aggregate exposure to a level of concern, since the combined aggregate residential and chronic dietary exposure to all agricultural applications of streptomycin, including the proposed use of streptomycin on citrus crops is 2,491 times less than the No Observed Adverse Effects Level (NOAEL) for the total U.S. population and 719 times less than the NOAEL for the most affected population subgroup, non-nursing infants. Dietary intake of streptomycin does not constitute a source of selection pressure for streptomycin resistance among enteric gut flora, since the dietary exposure from streptomycin applications to plant agriculture is so low and oral absorption for streptomycin is extremely low (<1%). Recent studies have revealed streptomycin-resistant isolates of many plant pathogenic bacteria exist as stable populations in the environment, even where streptomycin has never been applied, giving indication that factors other than streptomycin applications in the field influence the emergence of streptomycin resistance among plant pathogenic bacteria.”

Similarly, the R.E.D. publication for oxytetracycline says that the “use of the active ingredients hydroxytetracycline monohydrochloride and oxytetracycline calcium in accordance with approved labeling will not result in unreasonable adverse effects to human health or the environment.” Facts pertaining to risks have also been addressed in association with the potential for increasing the risk of human resistance to oxytetracycline in EPA’s TRED for oxytetracycline, as well as the FDA #152 assessment. The EPA oxytetracycline TRED concluded that “because anticipated dietary residues are extremely low, it is unlikely that antibiotic resistance from pesticidal use of oxytetracycline would result from food exposure,” and “the drug dose is 50,000 times greater than the estimated pesticidal dietary exposure (25 mg/kg/day dose divided by maximum aggregate dietary exposure of 0.000473 mg/kg/day). The small dose from pesticidal exposure would not be expected to select for resistant bacteria because very few bacteria would be killed by this small dose.” In the latest oxytetracycline dietary risk assessment, the drug dose is nearly 82,000 times greater than the estimated pesticidal dietary exposure [25 mg/kg/day dose divided by maximum aggregate dietary exposure of 0.000305 mg/kg/day for non-nursing infants (the highest population sub-group)]. Therefore, anticipated dietary residues of oxytetracycline are extremely low, and it is also unlikely that antibiotic resistance from the pesticidal use of oxytetracycline would result from food exposure.

The AgroSource oxytetracycline FDA #152 study summary paper notes that “oxytetracycline has been safely and effectively used in plant agriculture for more than 40 years yet a connection to the emergence of oxytetracycline resistance among clinical pathogens remains undocumented. EPA has previously determined that dietary exposure to oxytetracycline is below its level of concern. The use of oxytetracycline to combat HLB in citrus crops does not significantly increase the chronic aggregate exposure to oxytetracycline. Dietary intake of oxytetracycline is not expected to constitute a source of selection pressure for oxytetracycline resistance among enteric gut flora since the combined aggregate residential and chronic dietary exposure to all agricultural applications of oxytetracycline, including the proposed use of oxytetracycline on citrus crops, by non-nursing infants is 164 times less than the NOAEL, and approximately 82,000 times less than the commonly prescribed therapeutic dose for this most affected population subgroup.”

As a condition of the approval of a Section 18 exemption for the use of FireWall™ 50WP for the management of citrus canker (*Xanthomonas citri* pv. *citri*) on commercially-grown grapefruit in Florida, field studies were conducted during the 2014 season designed to detect potential development of streptomycin resistance in the culturable microbial communities from both phyllosphere and rhizosphere zones of FireWall™ 50WP treated (tested) and untreated (control) trees. Two commercial grapefruit grower cooperators provided a total of five unique test sites, all located within the Indian River Citrus growing region of southeastern Florida. No test site had previously received any treatments with streptomycin or streptomycin-based products. FireWall™ 50WP was applied to the test sites following the Section 18 label directions. Samples for culturable bacteria (as found in soils from beneath each tree and leaves taken from each tree) were collected at four dates beginning in August 2014 (T0) and ending in December 2014 (T3). Samples from all FireWall™ 50WP treated and corresponding untreated plots were analyzed for evidence of streptomycin-resistant bacteria. When the data were analyzed across all five test sites, results indicated no consistent and significant change ( $p=0.05$ ) in phyllosphere or rhizosphere microbial populations. More importantly, results revealed no evidence for development of streptomycin resistance among bacterial populations resident in FireWall™ 50WP treated grapefruit trees or soils in response to the use of FireWall™ 50WP on Florida grapefruit for management of citrus canker.

### **Mycoshield®**

Mycoshield® is currently registered for use on apples, pears, peaches and nectarines. Occupational exposure and risk are not expected to exceed the Agency's level of concern since airblast application at the same maximum rate of 1.5 pounds of formulated product per acre per application is already registered for peaches, nectarines and apples. EPA stated in the 2008 Health Effects Division (HED) Scoping Document for Registration Review of oxytetracycline that an

occupational assessment was not needed because of the low level of exposure anticipated from application of oxytetracycline products and the personal protective equipment required by the Section 3 label that includes protective clothing, chemical-resistant gloves, protective eyewear and a respirator. The occupational exposure and risk associated with the proposed Section 18 use on Florida citrus is therefore expected to be well below the Agency's level of concern.

The proposed time-limited tolerances of 0.4 ppm for residues of oxytetracycline in or on orange, Crop Subgroup 10-10A, and grapefruit, Crop Subgroup 10-10C, are based on data available to date from the ongoing magnitude of residue study (included in the Appendix E). Twelve foliar airblast applications of Mycoshield<sup>®</sup> were made at the maximum use rate of 1.5 pounds of formulated product per acre per application with a 2-day retreatment interval plus two trunk applications of Mycoshield<sup>®</sup> at 1.5 pounds of formulated product per acre per application. This resulted in a total application rate of 21 pounds of formulated product/acre (3.57 lb. oxytetracycline/acre) whereas the proposed Section 18 label limits application to 12 pounds of formulated product/acre (2.04 lb. oxytetracycline/acre) total per year.

In the 2008 EPA Health Effects Division's Scoping Document for Registration Review of oxytetracycline, EPA concluded that expected dietary (food and water) risk for the U.S. population and all subpopulations was conservative and below the level of concern. Acute dietary exposure was not estimated because no acute toxicity was identified in any of the relevant studies in the oxytetracycline database. As a result, EPA determined that acute dietary risks are not of concern.

In order to investigate potential exposure and risk associated with the proposed Section 18 use on Florida citrus, Nufarm sponsored a chronic aggregate dietary assessment for currently registered uses of oxytetracycline and the proposed use on citrus in Florida. The available data from Nufarm's residue study on citrus were used to assess dietary exposure. The resulting chronic risk estimates are not of concern for any population assessed. Based on this assessment, there are no dietary exposure issues that would preclude the specific exemption use on citrus trees in Florida. Since there is no residential use of oxytetracycline, an assessment that aggregates more than food plus water is not needed.

A drinking water exposure assessment was also conducted for currently registered uses of Mycoshield<sup>®</sup> and the proposed Section 18 use on Florida citrus trees. The resulting drinking water concentrations were used in the dietary risk assessment. Concentrations were calculated to be very low or practically non-existent (report included in the aggregate dietary risk assessment). The impact of the Section 18 use on the ecological risk is not expected to exceed the Agency's level of concern. Oxytetracycline residues degrade rapidly in citrus foliage. As discussed in the section "Effectiveness of Proposed Use under Section 18", leaf residue analysis has shown that oxytetracycline residues were no longer detectable in foliage 10 days

after application to a grapefruit location and 4 days after application to an orange site.

Nufarm has responded to Data Call-In notices issued for the TRED and Registration Review of Oxytetracycline. Several studies including environmental fate and ecotoxicology studies were conducted to support the continued registration of Mycoshield®. Most of these studies have already been submitted to the EPA or will be submitted in the near future.

Regarding the potential for resistance development, it is unlikely that antibiotic resistance from pesticidal use of oxytetracycline would result from food exposure. Anticipated dietary residues for existing agricultural uses of oxytetracycline and the proposed Section 18 for Florida citrus are extremely low (conservatively estimated at 0.000076 mg/kg/day for the general U.S. population). The maximum aggregate dietary exposure calculated is very small when compared to pharmaceutical or veterinary doses. The small dose from pesticidal exposure would not be expected to select for resistant bacteria because very few bacteria would be killed by this small dose. An assessment of the potential for antibiotic resistance to develop as a result of the use of Mycoshield® on citrus was conducted following FDA Guidance #152 and is included in Appendix E-4. Additional information for Mycoshield® on these subjects can be obtained from Bill Bewlay with Nufarm.

### **Proposals to mitigate risks:**

Existing use restrictions already listed on both the streptomycin and oxytetracycline labels will further reduce risk. These label restrictions include: do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high watermark; do not contaminate water when disposing of equipment wash water; do not apply by aircraft; do not apply these products through any type of irrigation system; and, only three applications of streptomycin and three applications of oxytetracycline are allowed per season. Current labeling directives are sufficient to mitigate any potential risks. Full reports of tests and investigations made with respect to the safety of streptomycin and oxytetracycline, including all information pertaining to the methods and controls used in conducting these tests and investigations have been submitted and reviewed by the Agency.

The enforcement analytical methods for both products are available to monitor residues of streptomycin and oxytetracycline in citrus.

### **FQPA INFORMATION (OCTOBER 24, 1996 EPA LETTER)**

EPA requested that additional information be submitted with Emergency Exemption requests to address new risk considerations associated with requirements of the Food Quality Protection Act. This information has been provided to the Agency. Since these products are approved for other Section 3 registrations an initial FQPA review has already occurred.

### **COORDINATION WITH OTHER AFFECTED FEDERAL, STATE, AND LOCAL AGENCIES (166.20(a)(8))**

As EPA's state lead agency, the Florida Department of Agriculture and Consumer Services should provide this information.

### **NOTIFICATION OF REGISTRANT (166.20(a)(9))**

AgroSource, Inc. and Nufarm Americas Inc. have been notified of this request. The companies are supportive of this emergency exemption petition (see the Appendix for registrant support letters).

## **DESCRIPTION OF ENFORCEMENT PROGRAM (166.20(a)(10))**

As EPA's state lead agency, the Florida Department of Agriculture and Consumer Services should provide this information.

## **REPEAT USES (166.20(a)(11))**

This is the first request for the use of each of the requested products, streptomycin and oxytetracycline on citrus by Florida for management of HLB and improvement of overall citrus tree health. The use of antibiotics under this Emergency Exemption Request will suppress HLB in new growth but will not cure the infection in the branches, trunk and roots. The reservoir of bacteria in the lower portions of the tree is a source for constant reinfection. Even new plantings are subjected to continuous pressure from 'hot' psyllids. A Section 18 Emergency Use Exemption would be needed until the Section 3 registrations are obtained.

## **PROGRESS TOWARD REGISTRATION (166.25(b)(2)(ii))**

### **FireWall™ 50WP and FireLine™ 17WP**

AgroSource, in conjunction with the IR-4 Project, continues to make progress toward new registrations for the use of streptomycin and oxytetracycline on the citrus crop group and a variety of other crops. The company is preparing or has prepared and submitted the necessary documentation for a Section 3 registration for citrus. The application to amend the Section 3 label for streptomycin has been submitted to EPA (Decision Number: 486863) and a Pesticide Registration Improvement Extension Act (PRIA) due date of 05/04/2015 had been assigned. EPA subsequently decided to require that this request go through a "public participation process". As part of preparation for this process, EPA issued a deficiency letter to AgroSource (to provide more benefits information) and both parties "mutually agreed" on a new PRIA date of June 2016. Subsequently, the new submission goal for oxytetracycline on citrus is now October 1<sup>st</sup>, 2015 and for streptomycin the new citrus submission goal is November 1<sup>st</sup>, 2015.

### **Mycoshield®**

A GLP residue study on citrus fruit sponsored by Nufarm Americas Inc. was initiated in March 2015 to support the registration of Mycoshield® on the Citrus Fruit Crop Group 10-10. The study is expected to be completed by the end of June 2016. It will then be submitted to the EPA in support of a tolerance petition and Section 3 registration application. Nufarm anticipates submitting the application by August 1st, 2016. Assuming a timeline of 15 months for the EPA review, the registration could possibly be granted by the end of November 2017.

Nufarm is the basic registrant for Oxytetracycline Calcium and is responding to Data Call-In notices issued for the TRED and the Registration Review of Oxytetracycline. Several studies were required including environmental fate and ecotoxicology studies that also support the Registration Review of Oxytetracycline Hydrochloride (Appendix E-5).

#### **NAME OF PEST (166.20(b)(1))**

##### **Scientific Name:**

*Candidatus Liberibacter asiaticus* (CLas)

##### **Common Name:**

Disease:

Huanglongbing (HLB) or Citrus Greening or Yellow Dragon Disease

Vector:

Asian Citrus Psyllid (ACP) (*Diaphorina citri* Kuwayama)

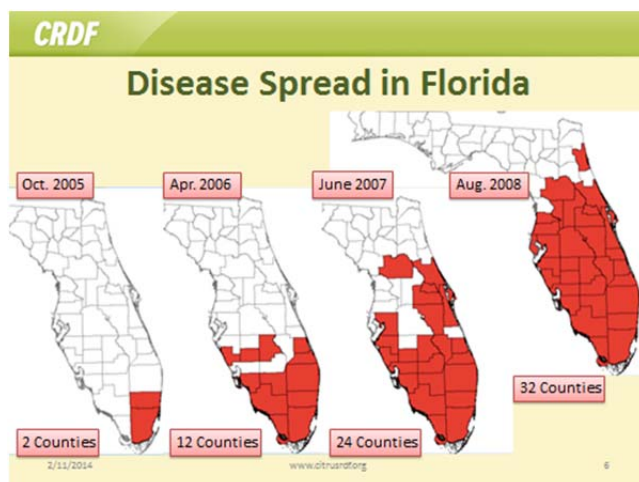
#### **DISCUSSION OF THE EMERGENCY CONDITION (166.20(b)(2))**

Citrus huanglongbing has been known in China for more than 100 years. In 1929, a disease with similar symptoms appeared in South Africa and was named 'yellow branch' in Western Transvaal and 'greening' in Eastern Transvaal. The agent associated with the disease was transmitted by graft-inoculation from citrus to citrus for the first time by Lin in China in 1956. This work remained unknown outside China; McLean and Oberholzer demonstrated independently that South African greening was graft-transmissible. Because 'huanglongbing' was the name used in the paper describing graft-transmission of the agent for the first time, it has priority over other names and has been unanimously adopted as the official name of the disease by the International Organization of Citrus Virologists (IOCV) at the 12th Congress of IOCV, Fuzhou, China, 1995.

In the 1960s, the agent was shown to be transmitted by two insects: the African citrus psyllid *Trioza erytreae* in Africa and the Asian citrus psyllid *Diaphorina citri* in Asia.

Symptoms of HLB were reported in Sao Paulo state in Brazil in 2004. Then, in 2005, HLB, was found to be present in Florida. This disease is caused by the pathogen *Candidatus Liberibacter asiaticus* and is spread by the Asian citrus psyllid (*Diaphorina citri* Kuwayama), which is an invasive pest to Florida, first discovered in 1998. HLB is considered to be the most serious disease of citrus worldwide and has greatly limited commercial production of citrus in countries where it is present. Since its discovery in Florida, this disease has rapidly spread throughout citrus production area to all

commercial production areas in the state. The graphic below illustrates the rapidity with which HLB invaded Florida commercial citrus counties:



(Source: CRDF Presentation to EPA, February 5, 2014)

HLB is a prime example of how an unintentional, but illegal, plant introduction into a country can cause multi-billion dollar crop losses, unemployment and industry-wide financial strain. The HLB bacterium lives in the vascular system component (phloem) that conducts synthesized food materials from the tree to the roots. Like the human blood vessels, a blockage of these vascular system conducting tissues by any foreign substance produces deleterious effect. The presence of CLas in the phloem prevents the tree from effectively transporting water, nutrients and minerals between the leaves, fruit and the roots in the ground, thereby driving the tree into decline. Since this disease's appearance, citrus production has been compromised with the loss of millions of trees, and HLB has subsequently been detected in every county with commercial citrus and in residential dooryard citrus as well. Trees infected with HLB will continuously decline and eventually die, even when incorporating all management options available to the industry at this time. The HLB-causing bacterium found in Florida is the Asian species that occurs in warm low altitude areas. HLB survives and multiplies within the psyllid vector throughout the psyllid's lifetime. The psyllid was first found in Florida in June 1998.

The severity of HLB and declining tree health far exceeds that of any previously known citrus disease, and all citrus species and their hybrids are confirmed to be affected by HLB. Infected trees first produce leaf symptoms; typically leaf yellowing on one or more branches, then leaves develop a blotchy (irregular spotted) appearance with grades of color. Infected trees typically also show symptoms that resemble micronutrient deficiency, especially, zinc and manganese. Fruit set becomes thin, fruit appear lopsided, the lopsided fruit may contain aborted seeds, and juice quality is unacceptable.

Impacts from HLB are numerous. On infected trees fruit are few in number, small, lopsided with a curved central core, and they fail to color properly, remaining green at the stylar end (hence the name "greening"). Excessive fruit drop occurs prematurely on

afflicted trees, and this has been reported in the past three harvest seasons in Florida to exceed 10 percent per season across all varieties. Even if fruit remain on the tree until harvest, the fruit are undersized and contain bitter juice, rendering it of reduced economic value. From a fruit size standpoint, HLB-infected trees have a significantly greater portion of fruit in smaller size categories compared to healthy trees (more than 95% of symptomatic fruit are less than 2.25 inches in diameter). Total juice volume produced is less from HLB-positive trees because of the smaller fruit size as well. Extensive research has been done to characterize the off-flavors associated with HLB-infected trees, highlighting both the general brix/acid ratio impacts as well as the components that contribute to flavor. This work is presented in detail by Baldwin, et al. 2010, Ikpechukwu et. al, 2011, Plotto et. al., 2013 and Massenti et. al. 2015.

HLB disease and the lack of any tree health improvement antibiotic has already pushed untold numbers of farmers out of the industry. Between 2004 and 2014, the amount of Florida land planted with citrus shrunk by nearly one-third, from 748,555 acres down to 515,147 acres (USDA, FASS). During that same timeframe, overall citrus production in the state dropped from 292 million boxes of fruit down to 124 million boxes (a 58% reduction). Average orange yields sunk from 428 boxes per acre in 2004 down to 250 boxes an acre in 2014 (a 42% reduction), despite the higher-density new plantings of orange trees, almost solely resulting from HLB infection.

Also contributing to the situation (and the continued higher grove maintenance costs) are Asian citrus psyllid management requirements. Since the psyllid's discovery, annual production costs have more than doubled. The majority of these increased costs are derived from psyllid management requirements and the necessary modified cultural practices. Psyllid management is an absolute necessity with respect to controlling HLB spread; the threshold for psyllid treatment has become "less than zero" in the industry. A high proportion of psyllids are now infected with the bacteria and capable of transmitting the disease. Florida citrus growers are currently spending more than \$240 million a year on insecticides directed solely to manage psyllids, which is about 30 percent more than they were spending in 2004, even though they're farming about 30 percent less land and yielding half as much fruit.

Citrus production and research experts believe that looking forward, the pursuit of interventions to reduce Asian citrus psyllid populations, reducing HLB bacterial populations within infected trees, and promotion of optimal tree health in the presence of HLB are the keys to the citrus industry's sustainability. The industry to this point has pursued a three-pronged approach to combating HLB, focusing on interventions on the three components of the disease pathosystem. The first component involves managing the psyllid. The second is understanding the bacterium itself, with the goal of hopefully neutralizing impact on psyllids or trees. Access to antibiotic materials such as streptomycin and oxytetracycline is vital to induce the improvement of tree health and subsequently keep trees viable until these other HLB management approaches can be developed. The third component is to breed new citrus trees that will hopefully tolerate or resist infection.

HLB is truly a limiting factor for citrus production. In the attempt to improve tree health to the degree possible, cultural practices such as foliar micronutrient sprays are employed once HLB infects a tree, but these effects are short-lived and certainly will not sustain the industry. HLB is already directly responsible for the loss of thousands of acres of Florida citrus trees. An emergency exemption involving multiple antibacterial strategies that enables improved fruit production must be gained in order to counter the impact of this bacterium/vector complex that is threatening the short- and long-term viability of the state's \$7 billion citrus industry. Without such antibiotic access and without anything else changing, within five to eight years of becoming infected, diseased trees will no longer be economically productive.

Limitations on replanting to replace declining tree inventories have made it critical to extend the productive life of the more than sixty million mature citrus trees in commercial groves. Continued production from this inventory of mature (infected) trees while new trees come on line is the process by which the Florida citrus industry can avoid failure and loss of critical nursery, production, harvesting, processing, packing and marketing infrastructure.

## HLB infection rates in new plantings

### Groves ~2 years of age (2014)

Psyllid pressure	HLB infection range	Average infection rate	# of groves
1 - low	0 – 4.05%	1.02%	20
2 – medium	1.73 – 65.6%	17.7%	20
3 - high	0 – 36.9%	20.96%	21



The graphic above emphasizes the point that despite ACP management programs, new plantings are still becoming infected and these would be primary targets for bactericide treatment.

## Biology of CLas and Disease Onset/Progression

The complicated biology of HLB and the interactions between vector, pathogen and host citrus plant make development of solutions challenging. Following inoculation of CLas into uninfected citrus trees, a period of latency follows during which time there is no

evidence of infection. Early symptom development is manifested through mottled foliage, followed progressively by smaller and narrower leaves, reduced mature fruit size and thinning of canopies. Chronic symptoms include limb dieback, fruit yield and quality reduction, and pre-harvest shedding of mature fruit. The time period of this disease progression varies with tree age and inoculum pressure, but generally in mature trees chronic decline appears within three to four years of initial infection.

### **New information on Root Impacts**

Research reported over the past three years (Graham et. al., 2012, Johnson et. al., 2014, and Graham and Morgan 2015) has revealed that CLas infection of citrus involves early movement of bacteria to root systems, where direct impacts on root health result. Root systems of infected trees have relatively fewer feeder root densities, diminishing water and nutrient uptake efficiencies and exposing diseased trees to additional stress. Further evidence from field research has demonstrated that HLB-infected trees are susceptible to lower populations of Phytophthora propagules than healthy trees, indicating that HLB infection allows soil diseases to overcome or break rootstock tolerance.

Significant economic loss has been experienced through lower fruit quality and smaller fruit size as described below, and proposed bacterial therapies have the potential to improve this aspect of the disease as root systems are restored. Strategies that address reduction in CLas titers in infected plants are few, but focus on reduction of bacterial levels early in disease development.

While research continues to further elucidate the impacts of early migration of CLas into root systems, it has become necessary for growers to apply additional treatments for Phytophthora, root weevils and other soil stressors. It is expected that this root health compromise will also impact the ability of citrus trees to respond to weather disruptions like freeze events or sustained heavy rainfall.

### **Non-Routine Emergency Situation:**

The rapid decline of HLB-infected mature citrus trees as evidenced by reduction in fruit size and quality and with the dramatic increase of fruit drop as fruit reaches harvest maturity.

Dr. Ariel Singerman of the University of Florida, IFAS, Citrus Research and Education Center has updated grower estimates of the spread of HLB in Florida and its impacts on production. This study is included in the Appendix and is posted at <http://www.crec.ifas.ufl.edu/extension/economics/>. Here are highlights regarding HLB incidence in Florida:

- 57 percent of growers surveyed report that 100 percent of their groves were infected, while 24 percent and 13 percent reported 80-99 percent and 60-80 percent infection, respectively.

- On a tree-by-tree basis, 15 percent reported 100 percent of their trees were infected, while 49 percent and 21 percent reported 80-99 percent and 60-80 percent tree infection rates, respectively.
- 80 percent of respondents reports yield losses in the range of 20-60 percent, with 13 percent of respondents reporting more than 60 percent yield loss.

These estimates reinforce official crop production figures from USDA/FASS reported elsewhere in this petition and highlight the level of impact on individual growers as the disease decline continues.

#### **DISCUSSION OF ECONOMIC LOSS (166.20(b)(4))**

The damage resulting from HLB infection is considerable. Diseased trees decline, yields are reduced, and fruit quality is affected. As the disease severity increases, yield is reduced through a combination of smaller crop set, preharvest fruit drop from affected branches and smaller fruit size. The yield reduction can reach 30 to 100 percent, depending on proportion of affected canopy. This level of disease progression makes the grove economically nonviable 7 to 10 years after planting. As disease severity increases, the percentage of affected fruit increases, reaching more than 40 percent. The affected fruit are smaller, lighter, very acidic, with reduced Brix, ratio, percentage of juice and soluble solids per box, and juice quality is negatively impacted. Millions of citrus trees in Florida have been affected by HLB and subsequently destroyed. The last projected value that has been established as a direct cost of HLB to Florida's citrus industry is around \$300 million annually.

The loss of production is felt by more people than just the famers that grow citrus. As production declines, packing houses do not run, box makers do not sell their products, shipping companies do not operate, etc.

Dr. Ariel Singerman, Assistant Professor of Agricultural Economics at the University of Florida, IFAS, Citrus Research and Education Center, has recently evaluated the impact of HLB on citrus production costs across the three general production regions of the state. His work is posted on <http://www.crec.ifas.ufl.edu/extension/economics/>. Below is a summary of Dr. Singerman's findings from citrus production operations in the three regions:

#### **Central Florida (Ridge) Cost of Production for Processed Oranges:**

The Table below shows total costs growers incurred for 2014-15, which includes cultural costs, tree replacement plus other costs such as management, regulatory and opportunity costs. The total cost of production for processed oranges for 2014-15 is reported to be \$2,282.19 per acre. Contributions to cultural operations include foliar

sprays at \$705.30 per acre; Citrus Health Management Area (CHMA) sprays \$56.65 per acre; fertilizer expense at \$469.80, and weed control at \$246.31. With thinner tree canopies and open spots where HLB has caused tree death, even weed management costs have escalated. This can be compared to production costs averaging \$700-800 per acre prior to HLB.

**Table 6: Total Costs of Production per Acre for Processed Oranges in Central Florida (Ridge), 2014/15.**

<b>Total Cultural Costs with Tree Replacement</b>	<b>1819.74</b>
<u>Other Costs</u> Interest on Operating (Cultural) Costs	90.99
Management Cost	81.75
Property Tax/Water Management Assessment	35.37
Interest on Average Capital Investment	254.34
<b>Total Other Costs</b>	<b>462.45</b>
<b>Total Costs</b>	<b>2282.19</b>

Southwest Florida Cost of Production for Processed Oranges:

Similarly, costs for production of oranges in southwest Florida continue to climb, in the Table below excerpted from this section of the Singerman report. In this case, foliar sprays average \$666 per acre plus \$20.55 for CHMA sprays. Fertilizer costs were \$486.90 per acre, and weed control averaged \$248.19. The total cultural operations costs of \$1,998.10 per acre are more than double those experienced prior to HLB impact.

**Table 7: Total Costs of Production per Acre for Processed Oranges in Southwest Florida, 2014/15**

<b>Total Cultural Costs</b>	<b>1998.10</b>
<u>Other Costs</u> Interest on Operating (Cultural) Costs	99.91
Management Cost	63.34
Property Tax/Water Management Assessment	28.73
Interest on Average Capital Investment	254.34
<b>Total Other Costs</b>	<b>446.31</b>
<b>Total Costs</b>	<b>2444.41</b>

Indian River Cost of Production for Fresh Grapefruit:

In the case of the Florida's premier production area for fresh grapefruit, the Indian River, the production costs mirror the increases observed in the other regions for processed

oranges, but are magnified due to the need for fresh fruit quality and its impacts on production costs. The Table below from the Indian River portion of the report indicates a total of \$2,478.61 cultural costs for 2014-15 and an overall per acre average production cost of \$3,073.38 per acre. Relevant operational costs are \$1,300.40 per acre for foliar sprays and \$14.75 for coordinated sprays (CHMA); fertilizer costs average \$452.55 per acre and weed control averaged \$190.60 per acre. This compares to fresh fruit production costs prior to HLB that averaged \$1,000-1,200 per acre per year.

**Table 8: Total Costs of Production per Acre for Fresh Market Grapefruit Grown in Indian River, 2014/15.**

Total Cultural Costs with Tree Replacement	2478.61
Other Costs	
Interest on Operating (Cultural) Costs	123.93
Management Cost	75.00
Property Tax/Water Management Tax	18.50
Fly protocol	16.00
Water Drainage District Assessment	107.00
Interest on Average Capital Investment	254.34
Total Other Costs	594.77
<b>Total Grower Costs</b>	<b>3073.38</b>

Integrating the increased production costs for Florida citrus with statewide declines in per-acre yields illustrates the emergency status and the business failure that is being witnessed in Florida. Small- and medium-sized operations are economically abandoning blocks of citrus which have fallen below break-even levels for several consecutive years, reducing any further losses associated with continued investment in the face of continuing decline in production. An option considered by some is reduction in inputs to offset smaller crop size and quality. Experience over recent years indicates that this pull-back in intensity of management of tree health accelerates the disease decline and only hastens economic abandonment. At the same time, these unmanaged groves become a source for inoculum for the pathogen and reservoir for the vector ACP.

Large citrus operations in Florida are facing similar decisions on the declining return or loss due to HLB, and are risk assessing individual blocks each year to determine where investments are warranted. They, too, are removing groves that have fallen below economic return thresholds from active management.

This scenario also is not favorably affecting growers' interest in replanting, as the uncertainties of being able to sustain production on new trees is influenced heavily by their experience with standing groves. Data on declines in nursery tree production in the past year attests to this uncertainty, despite availability of industry and other incentive programs to replant. The health of Florida's citrus industry is usually mirrored in nursery production. As industry production falls or fruit prices weaken, citrus nursery tree orders suffer. A total of 54 citrus nurseries propagated 4,438,128 trees in 2014-15, which is a decrease (5.8%) from last year. Nursery activity was strong for several new nurseries

that began producing trees this year; 6 new nurseries accounted for over 5 percent of the total nursery propagations. Existing nurseries mostly saw a decline in budding and tree orders. A total of 33 nurseries had reduced production from the previous year and only 15 saw an increase. Overall, tree production based on reports decreased by 274,311 trees. Taking into account that six new nurseries contributed to the production figures, it signified a downward trend for most nurseries. (FDACS Budwood Certification Program, Annual Report 2014-15).

### **The Economic Impact of HLB on the Florida Citrus Industry:**

As described in a recent publication, this disease and the resulting loss of production cost the industry over \$7 billion in lost revenue by 2012 (Hodges A.W., Spreen T. H., 2012). This loss of production translates to more than 8,000 lost jobs over the same five-year period. As trees succumb to the effects of the disease, the industry is faced with the challenge of replanting groves to replace the lost production. Although these figures have not been formally updated, the losses have risen considerably since this analysis was published.

### **Economic Effects of HLB in Florida:**

Florida's iconic citrus industry is an essential part of the economy of Florida, especially in the 28 central and southern counties of Florida where citrus is grown and processed. The most recent study before HLB became endemic put the overall economic impact at \$8.91 billion and provision of 75,827 jobs.

However, in 2012 economists calculated that over \$4.5 billion in economic impact had been lost because of the effects of HLB on the Florida orange juice industry for the period 2006 to 2010. The report details the category of losses, i.e., direct economic impacts, indirect economic impacts and induced impacts. On average, Florida's economy suffered with the loss of \$908.2 million dollars each year, and 8,257 permanent jobs.

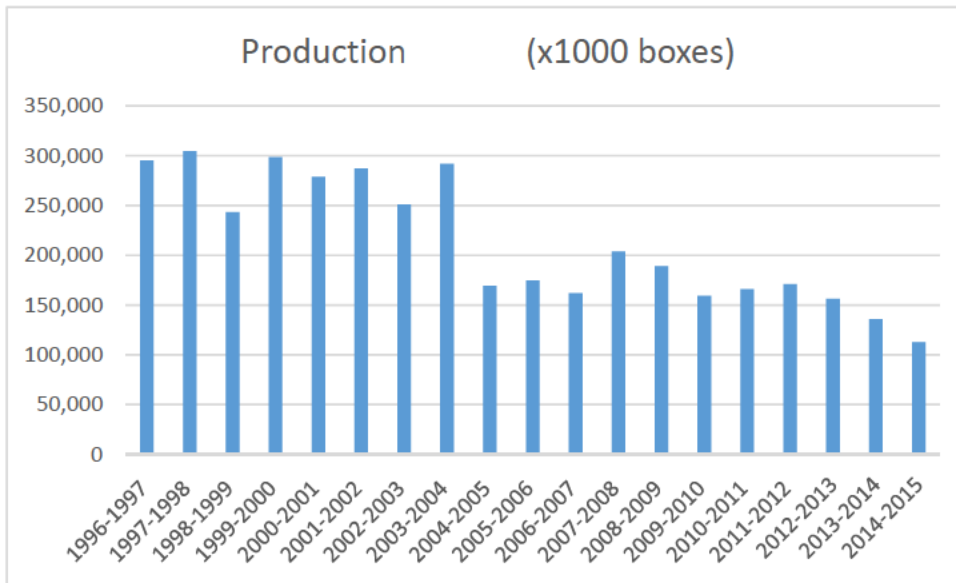
These losses are mainly because of the reduced production of Florida oranges versus a scenario without the effects of HLB in the citrus growing environment. Losing orange production is exacerbated by further losses of the value-added segment of the industry, that is fruit processing, juice manufacturing, and juice packaging and distribution. Since most of the orange juice sold in the United States is produced solely in Florida, this becomes a loss of economic benefits for Florida residents.

As the disease progresses, more losses are expected each year. An estimate of the most current losses are explained by looking at Florida citrus production statistics over the period prior to first detection of HLB in Florida (1996-1997 through 2005-2006) and the decline in production experienced in the recent three years as a result of both accumulation of disease across the state as well as the cumulative decline due to multi-year chronic HLB infection (Table 9).

**Table 9: Florida Citrus Production Statistics during the Period 1996-1997 through 2013-2014.**

<b>Crop Production by Fruit Type 1996-1997 through 2014-2015</b>				
<b>Crop Year</b>	<b>Oranges</b>	<b>Grapefruit</b>	<b>Other Citrus</b>	<b>Total</b>
	(1,000 Boxes)			
1996-1997	226,200	55,800	13,315	295,315
1997-1998	244,000	49,550	10,900	304,450
1998-1999	186,000	47,050	10,115	243,165
1999-2000	233,000	53,400	12,030	298,430
2000-2001	223,300	46,000	9,505	278,805
2001-2002	230,000	46,700	10,565	287,265
2002-2003	203,000	38,700	9,305	251,005
2003-2004	242,000	40,900	8,900	291,800
2004-2005	149,800	12,800	6,650	169,250
2005-2006	147,700	19,300	7,600	174,600
2006-2007	129,000	27,200	5,850	162,050
2007-2008	170,200	26,600	7,000	203,800
2008-2009	162,500	21,700	5,000	189,200
2009-2010	133,700	20,300	5,350	159,350
2010-2011	140,500	19,750	5,800	166,050
2011-2012	146,600	18,850	5,440	170,890
2012-2013	133,600	18,350	4,280	156,230
2013-2014	115,000	16,500	4,400	135,900
2014-2015	96,700	12,950	2,980	112,630

Source: USDA, National Agricultural Statistics Service, FASS, Florida Citrus Statistics. 2011-2012, published February 12, 2013. Data for crop years 2012-2013 and estimates for 2013-2014 provided by USDA, NASS, FASS, Citrus Forecast, January 10, 2014. 2014-15 July 10, 201 Final Forecast for Season.



Note: The above graph depicts the data in the table for total production, all varieties, and is included as an alternative data presentation, or to be used elsewhere in the petition.

Losses have now reached levels that annual citrus production is less than half of what it was as recently as 2003-2004. The decrease in fruit in successive harvests over the past three seasons is shown here:

<b>2010-2011 to 2011-2012</b>	<b>9%</b>
<b>2012-2013 to 2013-2014</b>	<b>11%</b>
<b>2013-2014 to 2014-2015</b>	<b>17%</b>
<b>Net loss (3 years)</b>	<b>= 34%</b>

With the rapid spread of HLB disease, and the increasing infection rates within standing groves, the situation that we are experiencing now in Florida is a combination of:

- Widespread infection of citrus trees throughout the growing region of Florida.
- Heavy inoculum in infected trees available for acquisition by the vector, ACP. Recent samples indicate up to 100 percent of field-collected ACP are positive for *CLas*, the pathogen.
- Limited removal of infected trees means that local spread can be rapid if psyllids are not managed effectively. With high rates of infection within a block, tree removal is not practical.

- The accumulation of years of progressive infection by CLas means that a higher percentage of trees are beginning to show chronic infection, including more widespread symptoms within trees, thinner canopies and impaired root systems.
- These factors all contribute to the reduced fruit production (yield), even though the official acreage of citrus plantings has not declined significantly in the last few years. And,
- Fruit quality is declining, in size, flavor and maturity.

Thus, the productive population of mature trees is declining in health and productivity, and will likely continue to do so without effective therapeutics, which currently are not available. In addition, new citrus trees that are either inter-planted in existing groves of mature trees or planted solid in new blocks are at high risk to infection via the ACP vector bringing inoculum from CLas reservoirs. It is these new trees that will provide the ability for economic production of citrus to continue, and the confidence to replant is, at present, limited by early and fatal infection of young trees by CLas through psyllid transmission. Trees in the first 4-5 years of growth are particularly vulnerable since they grow new flush off-cycle when other trees are not producing new leaves. This makes them more attractive to ACP colonization and vulnerable to disease transmission.

The importance of management of HLB in Florida citrus is reduced to two major considerations. The first is to delay further health decline in existing mature trees that will further erode production. Second, and more vital, is the ability to manage ACP populations in young plants, thereby providing confidence to growers to replant. Both of these considerations could be positively impacted by availability of effective bactericides.

### **Consideration of Expected Economic Benefits of Improved HLB Management, Particularly Through Availability of Bactericides**

This overview adds insights by attempting to quantify potential economic benefits to Florida if research efforts change the trajectory of any one of several factors that affect the economic impact of citrus production (specifically oranges) in the state. The initial overview focuses on the various aspects of production, such as acreage, yields, fruit loss to drop and quality reduction and other measures of decline due to HLB that would be expected to show improvement with implementation of an effective bactericidal program, as well as the trends in replanting, which likewise would be expected to improve as bactericidal therapy is made available.

To understand the economics of expected response to exposure of HLB-infected trees to a time course of one or more bactericidal treatments, it is important to outline the disease progression associated with this disease and to determine which aspects of the disease impact would be improved through treatment. As stated earlier in this petition, infection of citrus by *CLas* is initially invisible, followed in a multi-year time course by a series of symptoms and injury which begin as foliar mottling and chlorosis and progressing to reduction in canopy density, and leaf size, and overall appearance of decline in one or more branches of the infected tree. General decline reflects root injury and limited movement of plant products through the impaired vascular system. With time, the appearance of small fruit, further thinning of canopies, and leaf and premature fruit drop signal more advanced imbalance in the tree. Leaf symptoms also include general chlorosis (yellowing) and their noticeable appearance as thinned canopies, with bare patches within the canopy of chronically infected trees. These advanced symptoms, and the continued decline to death of chronically infected trees, may not appear for several years following infection, or even following first visual symptoms. The general decline is symptomatic of the breakdown of several plant systems, including roots (lower feeder root density), reduced vascular movement (phloem plugging) of nutrients from sources to areas of need (leaves to roots, roots to developing fruit, etc.), and impaired photosynthesis due to canopy loss.

Thus, in evaluating the expected response to treatment of *CLas* in infected trees, the forgoing description also defines the measures necessary to determine stabilization or recovery from disease symptoms. Expected changes in the following parameters can be predicted from previous research on epidemiology of HLB in citrus and are the metrics associated with field evaluation of therapies as pursued by the registrants of the candidate bactericides.

- Reduction in *CLas* titer in infected trees following bactericidal regimen: The first measurable impact of bactericidal treatment would be expected to be reduction in bacterial titer in infected tissues. This is best measured at present using qPCR, and the numerical scale changes in samples over time reflect increase or decrease in bacteria in tissues sampled. Following a time-course of bactericidal treatments, it would be expected to see a gradual increase in PCR CT values, indicating a decline in titer in infected plant parts sampled. This may occur as step-wise reduction following individual applications, as evidenced in the data summaries provided. This in itself is not a metric of improved plant health or economic benefit, but portends resumption of growth and response as bacterial levels decline.

- Improved tree growth response: Biological response to the lessening of pathogen pressure in infected trees is manifest in a series of indicators that trees are returning to more normal growth and development. As in the description of the onset of disease symptoms above, the progressive lessening of disease injury would be expected to show itself through leaf, branch, root and fruit symptoms. This has been observed in field experiments where therapies (both chemical and thermal) have been applied, and specific field results are presented in this petition for the products being field tested.
- Foliage response: Larger, greener, more robust flush appear in flushing periods following treatment, and the degree to which flushing phenology and the strength of new foliage resume a “normal pattern” is indicative of reduced disease.
- Canopy density improvement: Increased photosynthetic capacity is a by-product of new, healthy flush and drives plant health. Tree growth, including laying down of new phloem also can follow.
- Root health improvement: Photosynthate movement and lessening of root decline due directly to CLas follows resumption of tree flushing, and it is yet unclear to what extent this will occur following a treatment regime of bactericides.
- Increased capacity to utilize irrigation and nutritional applications, including improved foliar uptake. Restoration of root health has immediate impacts on the tree’s ability to utilize nutrients and healthy roots buffer periods of dry and wet weather.
- Ability to combat other stresses (root disease, cold, drought). Resumption of balanced flush with restored roots has the added advantage of providing the defense against other stresses that exist in groves. Overcoming these stresses also contributes to resumption of tree health and productivity.
- Fruit set and productivity: Since successful fruiting is dependent on support from the canopy, the above improvements in tree health can be expected to contribute to improved fruiting, and in conjunction with lower CLas titer, less size and fruit quality issues. Metrics associated with fruit yield, size and quality thus are direct indicators of effect of treatment success.

It should be clear that expected response in diseased citrus trees from application of a regimen of bactericidal applications will first be improvement in bacterial titers, followed by reduced visual symptoms, then impacts on the production and quality of fruit. While

this is likely to occur across a full production season, it is also likely that accrued benefit of the suppression of CLas in infected plants will occur over multiple seasons.

While none of the above discussion pinpoints economic benefit of grower use of the proposed bactericides in this petition, it provides the context for that economic assessment. Based on the preceding discussion, improvement in tree health should lead to following economic drivers:

Fruit yield and quality improvement –

Larger fruit set and retention through the production season;

Increased capacity to hold fruit on the tree season-long; less pre-harvest fruit drop;

Improved fruit size;

Improved internal fruit quality;

Normal growth progression for young trees (up to 5 years old) to full productivity (multi-year impact); and,

Increases in new plantings with availability of tools to deter disease progression.

### **Impacts at the Processing Facility:**

The economic loss resulting from HLB-induced reduction of quality can be measured by downgrading, which initially can be done while fruit are still on the tree. Quality standards are established for juice fruit and fresh fruit harvest per fruit variety, and delays in maturity, caused by HLB infection, postpone harvest, and allow an extended period for pre-harvest fruit drop to occur. Increasingly, harvesting of fruit, even for processing, is not “clean-picked”, where the entire crop is removed at once, then graded and routed to fresh and processing streams. In the presence of HLB, fewer groves are harvested in this manner, and the fruit left behind due to irregular shape, small size, and other quality parameters is lost production.

Fresh-fruit harvest has traditionally used “spot-picking” to begin the season, where fruit of the desired size and maturity are harvested, allowing remaining, smaller fruit to “size up” and mature for later harvest. Under HLB conditions, some groves from which fresh fruit are harvested are spot-picked 3 times, dramatically increasing harvest and handling costs. In the past two seasons, fruit left after initial spot picking did not continue to size, another result of HLB disease. Ultimately, the remaining fruit on these trees are clean-picked for routing to processing plants.

The second stage for quality downgrading comes at fruit load receipt at either packing houses (fresh) or processing plants (juice). Typically, fresh packing operations sort, grade and pack cartons of fruit to specifications. The percent of fruit arriving at the packinghouse that ends up in cartons is referred to as pack-out. Even with spot-picking to select higher quality fruit, pack-out percentages have dropped 20 to 40% in the past 3

years. The fruit not packed into cartons is redirected to processing streams, resulting in lower returns. For the 2014 fruit season, oranges averaged \$16.31/box when utilized for fresh and \$12.09/box average for processing (USDA, NASS Florida Agriculture Quick Statistics). The differential is even greater for grapefruit, where 2014 fresh grapefruit were valued at an average of \$14.44 per box for fresh and \$6.38 per box for processing utilization.

Fruit arriving at processing plants is sampled by load and the quality is assessed. The FDACS State Test House measures percent brix (sugar), percent acid and the ratio of brix/acid. This ratio is the initial basis for juice quality, and provides the quality data for payment to the grower. Additional data recovered from the load sampling includes pounds solids per weight of fruit, percent juice and overall weight of the load. The formula for payment is quality based and calculated for the pounds solids delivered from the entire load.

HLB-affected loads of fruit net a lower brix and lower ratio, and due to smaller size, have less percent juice, yielding less juice from processing. Based on the State Test House results, fruit loads are assigned a grade, and lower grades are discounted. In the case of shared pool processing situations, the grade determines your "pool share" at season's end, and this can be as much as 15-20 % discount for grade B compared to grade A fruit loads. The more serious impact is when lower grade loads of fruit are routed for juice concentrate production rather than inclusion in the not-from-concentrate juice processing stream. A significant differential occurs between these two forms of orange juice utilization, and this varies by processor and by season.

All of these parameters have declined progressively over the past 3 years, and are expected to continue in chronically infected trees. Treatment to suppress HLB in these infected trees would be expected to reverse this process and restore value for each of these variables.

### **Impacts at the Fresh Fruit Packing House:**

In addition to the impact on the processing industry, the fresh fruit industry has paralleled the losses due to HLB.

The loss in fresh utilization is due to:

- Tree loss
- Increased fruit drop
- Lower pack outs, due to smaller size and quality issues associated with HLB.

**Table 10: Reduction in shipments of Fresh Fruit Varieties in Florida as a result of the impact of HLB**

<b>Change 2014-2015 from 2007-2008</b>		
<b>Variety</b>	<b>Fresh Boxes (In 000)</b>	<b>% Reductions</b>
Oranges	(476)	-10.8%
Grapefruit	(4,645)	-46.8%
Tangelos	(74)	-46.1%
Early Tangerines	(730)	-63.3%
Honey Tangerines	(909)	-63.3%
All Fresh	(6,834)	-38.6%

Data sourced from: Duke Chadwell, Citrus Administrative Committee

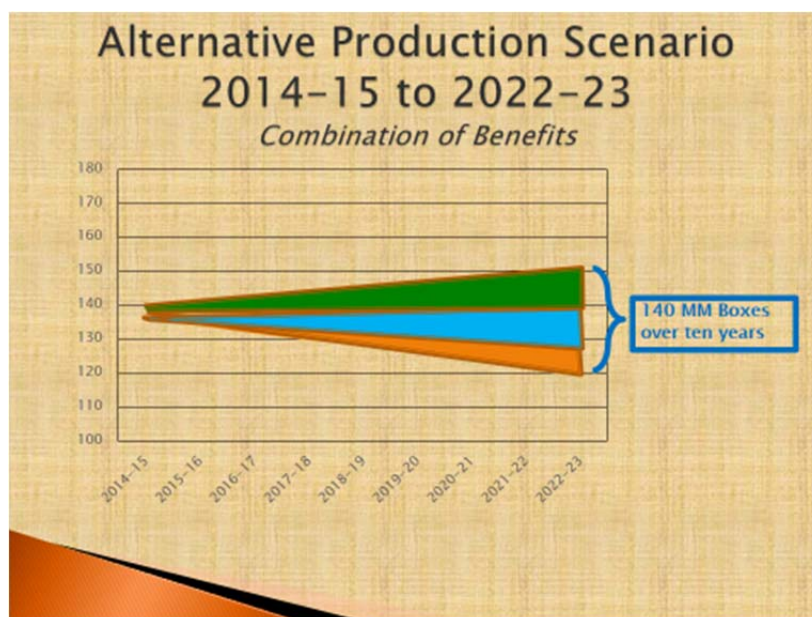
For one Florida shipper, the 3-year average pack out (fresh utilization) for the 2005, 2006, and 2007 seasons was 70.4%. The average pack out for the 2013, 2014, and 2015 seasons was 53.7%. This 16.7% pack out reduction is due to HLB impacts on the size and quality of fresh fruit produced from our groves.

Improving pack outs to pre-HLB levels would increase our company's fresh output by 126,487 boxes, or 33.0%, without considering any potential yield increases.

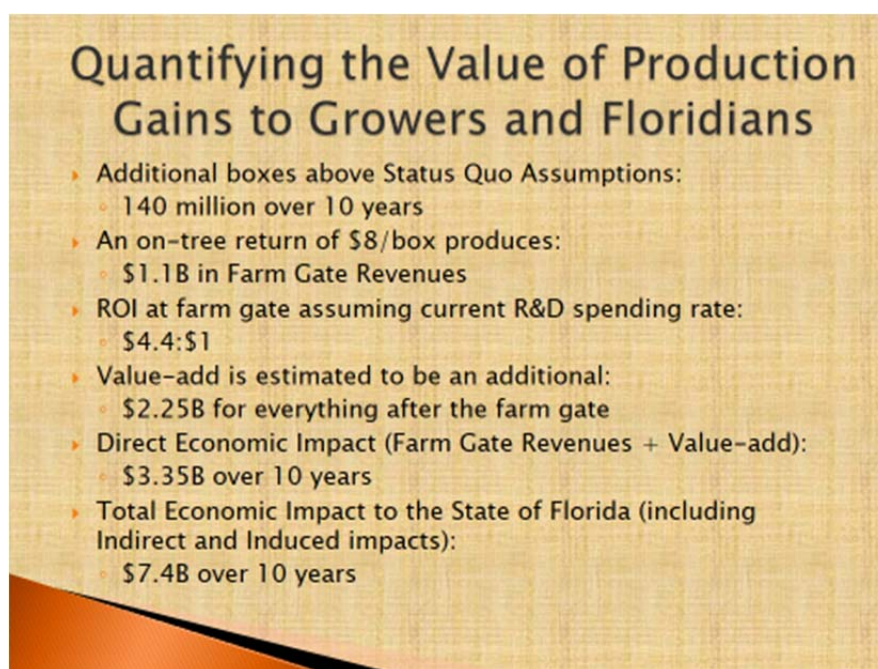
### **Industry Wide Impacts:**

The following is a summary of previously published and presented material supplemented with data from the 2012-13 fruit season. This report was prepared by Bob Norberg, Economist, Florida Citrus Mutual, Economic and Market Research Associates, January 2014. It summarizes several previously published reports regarding the economics of the Florida Citrus Industry and the impacts of HLB on Florida Citrus economics. Data from the most recent seasons is used to generate supplemental impacts based on the logic from the previous reports.

The three factors examined in this economic evaluation were: tree mortality rates, replanting rates, and fruit yields. Reducing the mortality, and/or increasing the replanting rate, and/or improving fruit yields all have positive economic impacts. The following chart shows the combined effects on crop size with gradual improvements to these factors over the next 10 years. Reducing the mortality rate from 4 to 3 percent in 10 years, increasing the planting rate from 2 percent to 3 percent over 10 years, and raising yields 1 percent per year would generate a total of 140 million additional boxes of fruit over the forecast horizon. Those additional boxes generate direct, indirect and induced economic impacts that would not be generated without them.



The following chart from the presentation concludes that those boxes are worth \$7.4 billion dollars during those ten years. Farm gate revenues would be enhanced by \$1.1 billion dollars.



Further increases in pre-season fruit drop and reductions in fruit size were forecasted in the January 2014 estimate highlighted in the table above and are expected to continue that trend in future production estimates. The reduced yields have contributed to the smallest orange crop since the freeze impacted crop of 1989/90. It is uncertain, but

likely, that these yield effects will be seen in future seasons without dramatic advances in production management practices, disease mitigation strategies, and solutions from the comprehensive research efforts.

#### **Update on Economic Impacts, January, 2014:**

Using the methodology previously established by Hodges and Spreen in their 2012 analysis, an updated estimate of the annual economic impacts of HLB (and other calamities) can be calculated. Although unit FOB values have risen recently, these increases do not compensate for the loss of volumes since the value-added portion of total economic output is a significant factor and is directly correlated to volumes of orange juice case goods produced and distributed.

The following table shows the losses to be \$3.3 billion over the period from 2011/12 to 2013/14 (January forecast) and 10,089 annual jobs. Combined with the losses estimated previously, losses to date from the 2006/07 season are \$7.8 billion.

The annual rate of losses in both economic output and jobs is accelerating from the previous estimate. The average annual loss was \$908.2 million per year between 2006/07 and 2010/11, while the annual loss rate for the period 2011/12 to 2013/14 is \$1.1 billion. Currently total economic losses versus a non-HLB forecast is estimated to be \$1.8 billion for the 2013/14 season based on the January crop forecast.

**Table 11: Impact of HLB to the Florida Citrus Industry the three Previous Seasons**

<b>CROP SEASONS 2011/12 – 2013/14</b>	<b><u>Non-HLB</u></b>	<b><u>HLB</u></b>	<b><u>Difference</u></b>
<b>FOB REVENUES (MM)</b>	\$7,356	\$6,103	(\$1,253)
<b>DIRECT ECONOMIC OUTPUT (MM)</b>	\$7,088	\$5873	(\$855)
<b>TOTAL ECONOMIC OUTPUT</b>	\$19,245	\$16,096	(\$3,329)
<b>ANNUAL EMPLOYMENT</b>	58,865	48,776	(10,089)

This information has not been updated to include the 17 percent production loss experienced during the 2014-15 citrus season.

**ESTIMATED REVENUES FOR THE SITES TO BE TREATED (166.20(b)(4)(ii) & (iii)) (166.20(b)(4)(ii) & (iii))**

Florida accounts for:

66 percent of the total U.S. value for oranges;

65 percent of the total U.S. value for grapefruit.

Florida currently ranks 1<sup>st</sup> in the U.S. in the value of both the production of oranges and grapefruit.

**Table 12: Florida Production Information, Oranges**

<b>Florida Orange Production Information*</b>					
Season	Total Bearing Acres	Total Production (1000 boxes**)	Yield per Acre (total boxes)	Price per Box	Total On-Tree Value (Millions)
2013-14	418,700	104,600	250	\$7.58	\$ 792.7
2012-13	429,200	133,600	311	\$7.43	\$ 992.5
2011-12	433,400	146,700	338	\$9.92	\$1,455.7
2010-11	440,000	140,500	319	\$8.41	\$1,181.9
2009-10	451,000	133,700	296	\$6.96	\$ 929.9
5-Year Average	434,460	131,820	303	\$8.06	\$1,070.5

\* Source: Latest Available Florida Agricultural Statistics Service Citrus Summary, February 2015.

\*\* Box = 90 pounds

**Table 13: Florida Production Information, Grapefruit**

<b>Florida Grapefruit Production Information*</b>					
Season	Total Bearing Acres	Total Production (X 1000 boxes)	Yield per Acre (total boxes)	Price per Box	Total On-Tree Value (Millions)
2013-14	43,100	15,650	363	\$6.44	\$100.8
2012-13	44,900	18,350	409	\$6.47	\$118.7
2011-12	45,500	18,850	414	\$7.17	\$135.3
2010-11	46,500	19,750	425	\$6.72	\$132.7
2009-10	48,100	20,300	422	\$7.50	\$152.2
5-Year Average	45,620	18,580	407	\$6.86	\$127.9

\* Source: Latest Available Florida Agricultural Statistics Service Citrus Summary, February 2015.

\*\* Box =85 pounds

Economics associated with HLB and potential impacts of Section 18 bactericidal treatments:

#### **Processed Oranges Metrics (>90% of Florida citrus Crop)**

**Table 14: Emergency Loss When compared to Baseline Florida Orange Production Prior to HLB.**

<b>Factor</b>	<b>Baseline (pre-HLB) 2005-06</b>	<b>2014-15 Harvest Season</b>	<b>Change (%)</b>
Bearing Orange Acreage	529,241 acres	441,628 acres	-16.6
Annual Production (million boxes)	147,700,000	96,800,000	-34.5
Yields per acre (90 lb. box)	301 boxes/acre	250 boxes/acre	-17
Fruit Size (average number/box)	221 (2007-08)	244	10.4
Pre-harvest fruit drop (Valencia)	15 % (2007-08)	25%	10

Source: USDA, Florida Agricultural Statistics Service

## **Expected Benefit Due to Bactericide Treatments:**

Expected impacts are calculated based on historic statistics and expected impacts of the proposed treatment on citrus productivity and fruit quality. The factors that are most likely to show improvement following season-long treatments as described in the petition are improvement in fruit size, retention of more fruit on tree, and return crop production increases.

Reduction in Fruit Drop: One of the most devastating impacts of HLB is loss of yield through fruit drop just prior to harvest. The impacts of 20 percent and 50 percent reduction in fruit drop are calculated here.

A 20 percent reduction in the current 25 percent fruit drop rate would restore five percent to harvested yield for the same crop load. This five percent retention adds 12.5 boxes per acre and at \$12.09, on-tree value of \$151.13 per acre. **That translates into 5,520,350 boxes of fruit saved from falling to the ground with a 25 percent reduction in the amount of fruit drop, and this is valued at \$66,743,240 for orange acreage per year.**

Using the same calculations for fifty percent reduction in fruit drop would restore 12.5 percent to yield. This translates into 31.25 boxes per acre additional impact on yield and, at \$12.09, is valued at \$378 per acre per season. **Calculated benefit across all orange acreage provides addition of 13,800,875 boxes of fruit, or an economic benefit of \$166,935,384 to Florida orange growers per season.**

Similar calculations can also be made for other citrus varieties and for the added value of fresh market, especially for grapefruit.

Improvement in Fruit Size: HLB has reduced fruit size, and tree health recovery is expected to improve fruit size. The impact is calculated for 20 percent reduction and 50 percent reduction in fruit size.

Comparison of fruit size shows 23 additional fruit were needed to fill a 90 pound box because of HLB in 2014-15.

A 20 percent treatment improvement in fruit size would lead to 4.6 fewer fruit per box (239.4 fruit/box), across 250 boxes per acre, for a total of 1,150 pieces, and at 239.4 fruit/box, this would add 4.8 boxes per acre. **The per-acre economic benefit of a 20 percent change in fruit size reduction would lead to 4.8 boxes x \$12.09 (on-tree price, 2014-15) or \$58.03 per acre. Across all orange acreage (441,628 acres), this benefit would be 2,119,814 additional boxes of oranges, and \$25,628,556 per season for just this minor improvement to fruit size.**

A 50 percent treatment improvement in fruit size reduction would similarly lead to 11.5 fewer fruit needed to fill a 90 pound box (232.5 fruit), across 250 boxes per acre, for a total of 2,875 pieces, and at 232.5 fruit/box, that improves yield by 12.4 boxes per acre. **The per-acre economic benefit of a 50 percent change in fruit size reduction would therefore lead to 12.4 additional boxes x \$12.09, or \$149.50 per acre. Across all orange acreage, this would add 5,343,699 boxes of yield worth \$64,605,321 per season at 2014-15 prices.**

Similar calculations could be developed for non-orange varieties, and additional value could be calculated for considering fresh fruit value-added for the portion of the crop that is marketed fresh.

Both of the above improvements to orange yields are possible within the existing crop load of fruit, and reflect within season improvements that could occur with effective bactericidal treatment. Additional value could be obtained with expected improvements in fruit quality (brix/acid ration, pounds solids and flavor-impacting components. These benefits are not included in the size and fruit drop considerations above.

Improved annual production (successive years): In crop years following application of the emergency treatments, it is expected that restored tree health would lead to higher fruit set and increased yields above and beyond the benefits discussed above.

Calculations of the value of this for varying rates of improved yield are:

Five percent yield response would increment yield of 250 boxes to 262.5 per acre, or an increase of \$151.13 per acre. **The all-orange impact would be 5,520,350 boxes and \$66,736.800 per season, the same benefit (additive) to the reduction in fruit drop.**

10 percent yield response would increment yield of 250 boxes by 25 boxes per acre, or \$302.25. **Across all orange acres, this 10% improvement in current tree productivity would add 11,040,700 boxes of fruit and an economic benefit of \$133,482,063 per season.**

25 percent yield response nets 62.5 boxes per acre additional fruit, or \$755.63 per acre benefit. Across all orange acreage, this estimated benefit is 27,601,750 boxes, or when added to 2014-15 season yields, 124,401,750 boxes per season. **The estimated economic value of the additional production improvement of 25 percent is \$333,705,158 per season.**

The actual benefit can be approximated by adding the improvement in fruit drop reduction, increased fruit size, and finally the gain in production that treatment to reduce CLas titer in infected trees might bring. Again, these calculations represent oranges and the acreage currently dedicated to this major element of the industry. Similar composite benefits could be calculated.

Using the minimal improvements calculated above (20% reduction in fruit drop, 20% improvement in fruit size reduction and 5% production increase in new crop) the economic benefit calculated for the orange acreage in Florida is \$66,743,240 + \$25,628,556 + \$66,736,800 or \$159,108,596 per season.

Finally, the treatment benefits would encourage new plantings, and the new benefit would then be multiplied as new plantings come into production.